SMARTsurg

SMart weArable Robotic Teleoperated surgery

D1.2: Ethics and Safety manual for SMARTsurg Technologies

Due date: M3

Abstract:

The present document is a deliverable of the SMARTsurg project, funded by the European Commission's Directorate-General for Research and Innovation (DG RTD), under its Horizon 2020 Research and Innovation programme (H2020). It provides the preliminary Ethics and Safety Manual for SMARTsurg technology, based on a thorough review of the ethical EU and national legislations and directives and the establishment of the SMARTsurg Ethics Helpdesk. This document also concentrates on safety issues in collaborative robots, presenting safety features according to relevant standards. Special attention is given to those characteristics that ensure human collaborators', such as the surgeons, safety and security. It is strongly emphasized that this is an ongoing document that will evolve along with the project progress and will be regularly updated in order to reflect up-to-date information.

Dissemination Level		
PU	Public	x
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Document Status

Document Title	D1.2 Ethics and Safety manual for SMARTsurg Technologies
Version	1.0
Work Package	1
Deliverable #	1.2
Prepared by	CERTH
Contributors	UWE, POLIMI, ALL
Checked by	UWE
Approved by	UWE
Date	31/03/2017
Confidentiality	PU

Contact Points

Coordinator		
University of the West of England BRISTOL	University of the West of England Bristol Robotics Laboratory T Building, Frenchay Campus BS16 1QY Bristol UK	Tel: +44 117 32 81301 E-mail: Sanja.Dogramadzi@brl.ac.uk Website:http://www.brl.ac.uk/research/researchthemes/medicalrobotics.aspx

Partners		
CERTH CENTRE FOR RESEARCH & TECHNOLOGY HELLAS	Information Technologies Institute Building A - Office 1.1A 6th km Charilaou - Thermi, 57001 Thessaloniki, Greece	Tel.: +30 2311 257777 Fax: +30 2310 474128 E-mail: tzovaras@iti.gr Website: www.iti.gr/iti
POLITECNICO MILANO 1863	Building 32.2 Department of Electronics, Information and Bioengineering Via G.Ponzio 34/5 Milan, Italy	Tel.: +39 022 399 3371 E-mail: giancarlo.ferrigno@polimi.it Website: www.nearlab.polimi.it
Bristol Urological Institute	Brunel Building, Southmead Hospital BS10 5NB Bristol, UK	Tel.: +44 117 4140898 E-mail: anthony.koupparis@nbt.nhs.uk Website: www.nbt.nhs.uk/bristol-urological-institute
University of BRISTOL	Tyndall Avenue Senate House Department of Clinical Sciences BS8 1TH Bristol, UK	Tel.: +44 117 3423286 E-mail: r.ascione@bristol.ac.uk Website:http://www.bristol.ac.uk/health-sciences/research/tbrc/
IEO Istituto Europeo di Oncologia	Division of Urology Via Ripamonti, 435 20141 Milan, Italy	Tel.: +39 0257489516 E-mail: ottavio.decobelli@ieo.it Website: www.ieo.it
TheMIS THESSALONIKI MINIMALLY INVASIVE SURGERY ORTHOPAEDIC CENTER	TheMIS Orthopaedic Center 6 Adrianoupoleos St. 55133 Thessaloniki, Greece	Tel.: +30 2310 223 113 E-mail: papacostas@the-mis.gr Website: www.the-mis.gr/site/en
cybernetix A Technip Company	306 Rue Albert Einstein 13882 Marseille, France	Tel.: +33 (0)49121 7775 E-mail: jvandenbosch@cybernetix.fr Website: www.cybernetix.fr
Optinvent	R&D Department Avenue des Buttes de Coesmes 80 35700 Rennes, France	Tel.: +33 299871066 E-mail: khaled.sarayeddine@optinvent.com

		Website: www.optinvent.com
HIT HYPERTECH INNOVATIONS	HIT Hypertech Innovations 10 Polytechneiou Str. 3083, Límassol, Cyprus	E-mail: contact@hit-innovations.com Website: www.hit-innovations.com

Document Change Log

Each change or set of changes made to this document will result in an increment to the version number of the document. This change log records the process and identifies for each version number of the document the modification(s) which caused the version number to be incremented.

Change Log	Version	Date
First draft	0.1	February 15, 2017
Updated	0.2	March 17, 2017
Partners' feedback	0.6	March 30, 2017
Updated	0.7	March 30, 2017
Final	1.0	March 31, 2017

Table of Contents

List of Figures

1. Introduction

1.1 Objective and Scope

The purpose of this deliverable (D1.2 – "Ethics and Safety Manual for SMARTsurg Technology") is to define the ethical activities of the SMARTsurg project and the safety issues that are associated with the project's activities, especially those involving the use of robots. Through the use of collaborative robots, the need for cages and other necessary safety measures will be eliminated, allowing human participants to interact with the robotic manipulators with safety. Nevertheless, through the necessary activities, procedures and experiments that will be carried out for the purposes of the SMARTsurg project, certain privacy and safety issues may arise. Thus, appropriate ethical and safety approvals of the proposed applications will be defined, as specified in "Annex I- Description of Action" (DoA) [1] of the SMARTsurg project, regarding the foreseen Trials and the project's pilot experiments.

In order to effectively deal with such matters, the consortium partners have defined a well-structured ethics and safety policy, a preliminary version of which will be summarized in the final section of this document, where the Ethics and Safety Manual is provided. In this way the consortium shows its respect to the European and national legislation regarding privacy and safety issues, as well as its concern about SMARTsurg's participants regarding their privacy and safety protection. Indeed, the EU has expressed its concerns for ethics and legal aspects of robotics in the society, as evidenced by the recently EU funded RoboLaw project. All applications of the technologies developed in SMARTsurg will be in line with the regulations of the EU regarding robotics applications. SMARTsurg aims to go beyond the current regulations by adhering to trends in the evolution of those regulations. It is strongly emphasized that this is an ongoing document that will evolve along with the project progress and will be regularly updated in order to reflect up-to-date information.

1.2 Document Structure

First of all, a summary of the ethical activities to be found in the SMARTsurg project is presented, to continue with the analysis of the ethics methodology followed by the SMARTsurg consortium. The basic steps of the SMARTsurg Ethics Methodology consist of a thorough review of the ethical EU and national legislations and directives, the establishment of the SMARTsurg Ethics Helpdesk as well as the presentation of its role and responsibilities, the internal reports process and the documentation and summary of results of the current methodology.

The second main part of this document concentrates on safety issues in collaborative robots. Basic features for ensuring safety in collaborative robots according to relevant standards are presented together with an overview of the robots used in the SMARTsurg project (KUKA LWR5, YuMi, Virtuose 6D Haption),. Special attention is given to safety in regards to human participants, such as surgeons and patients.

In the final section of this document, the Ethics and Safety Manual of the SMARTsurg project is presented, with a comprehensive set of guidelines and rules that will be followed towards 1)

preserving the privacy of the users, 2) ensuring their safety and 3) respecting their rights as volunteer participants.

1.3 Reference Documents

[1] SMARTsurg Grant Agreement, Annex I - “Description of Action” (DoA)

1.4 Acronyms and Abbreviations

Abbreviation	Definition
D	Deliverable
DG RTD	Directorate-General for Research and Innovation
DoA	Description of Action
EC	European Commission
EMC	Electromagnetic Compatibility
EU	European Union
IEC	International Electrotechnical Commission
pHRI	physical Human-Robot Interaction
R&D	Research & Development
T	Task
WP	Workpackage

2. Ethics

2.1 Introduction

For the purposes of the SMARTsurg project activities that include data collection, storage and processing will take place for the purposes of assessing the developed technology in terms of the effectiveness of the proposed solutions. Therefore, human participants will be involved in certain aspects of the project and data about those participants will be collected. As a result, privacy protection and confidentiality issues for volunteers regarding the collected data need to be carefully managed. Furthermore, volunteers will be informed about their rights and responsibilities vis-à-vis their participation in the studies. For this purpose, special guidelines will be set and presented in this deliverable in order for the procedures and rules to be followed by the partners and the participants involved in SMARTsurg activities.

2.2 SMARTsurg Ethics Methodology

SMARTsurg consortium is fully aware of the safety and privacy issues related to the technologies to be developed herein and respects the ethical rules and standards of the EC and member states. The ethics methodology to be adopted in this direction comprises 4 steps, which are depicted in Figure 1 and described in the paragraphs below.

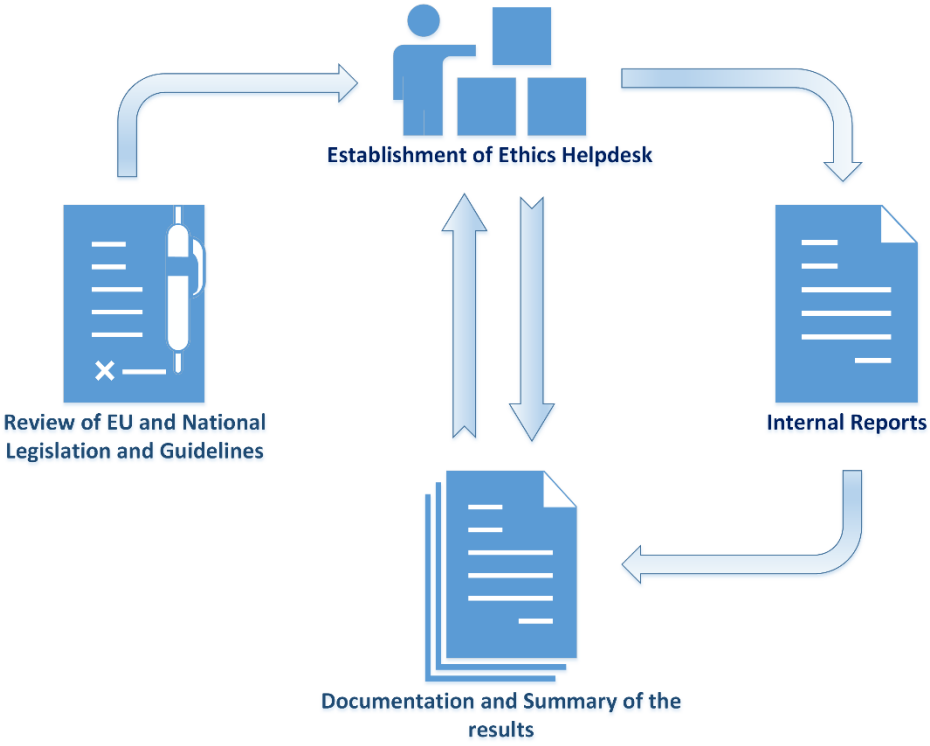

Figure 1: SMARTsurg Ethics Methodology

2.2.1 Review of EU and National Legislation & Guidelines

The consortium will carefully consider European and national legislation and directives relevant to the country where the data collections will place. The most important issues that are included in the national and international policies and will therefore be given special attention throughout this document are:

Voluntary Participation:

All SMARTsurg participants will take part in the project voluntarily, and no pressure will be forced on the employees of the pilot sites for participating in the project's activities. All participants will freely and willingly give their consent to be engaged to the SMARTsurg activities.

Informed Consent:

Every volunteer will give his/her informed consent to the consortium before the beginning of the tests, in order for the SMARTsurg project to assure the rights and dignity of those participants. Throughout the project's lifetime the rules and guidelines specified and defined in this document will be followed.

***Data protection**:*

For the collection and process of private data necessary for fulfilling the scope of the SMARTsurg project, the legislations and directives of the European Union as well as the national legislations of the countries where the pilot sites will take place will be followed. An overview of the relative legislation is provided in the following paragraphs of this document, while the set of guidelines produced is presented in the final section. It must be clarified that clinical testing is not considered within the context of the SMARTsurg project. However, data from real MIS operations may be employed for developing and testing methods and techniques employed by the SMARTsurg system. The acquisition and usage of such data will be made in accordance to both national and International legislation on privacy and data protection.

The process of adhering to the applicable regulations begins with a thorough investigation of the EU and National research projects' ethical guidelines as well as the examination of the directives regarding privacy and protection of personal data and free movement of data issues. The legislation with which the SMARTsurg consortium has to conform includes:

i) The Universal Declaration of Human Rights;

ii) The Convention 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data;

iii) The Directive 95/46/EC & Directive 2002/58/EC of the European parliament regarding issues with privacy and protection of personal data and the free movement of such data.

iv) The Declaration of Helsinki on research involving human subjects;

v) Good Research Practice at University of the West of England, relevant excerpts of the document (Annex III);

vi) The The UK Data Protection Act (https://www.gov.uk/data-protection/the-data-protection-act);

vii) The Charter of Fundamental Rights of the European Union (2000/C 364/01);UNESCO's Universal Declaration on Human Genoma and Human Rights;

viii) The Recommendation no. 10 dated 23/09/1983 of the Council of Europe – Committee of Ministers to Member States, relating to the protection of personal data used for purposes of scientific research and statistics;

ix) The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine – Oviedo 04 April 1997;

x) The Recommendation no. 10 dated 13/02/1997 of the Council of Europe – Committee of Ministers to Member States, relating to the protection of medical data;

xi) The international ethical guidelines on biomedical research drafted by the Council for International Organizations on Medical Sciences (CIOMS) jointly with the World Health Organization (WHO);

xii) The additional Protocol to the Council of Europe's Convention on Human Rights and Biomedicine, relating to biomedical research (2005);

xiii) Data Protection Code - Legislative Decree no. 196/2003);

xiv) Greek Law 2472/1997: Protection of Individuals with regard to the Processing of Personal Data;

xv) Greek Law 3471/2006: Protection of personal data and privacy in the electronic telecommunications sector and amendment of law 2472/1997.

A more thorough overview and analysis of the above mentioned legislation is as follows:

The SMARTsurg project abides by the European laws and directives as well as the national laws of the countries that are involved in the pilot studies or in other activities of the project. In this section, some key articles will be mentioned underlying the legal and ethical scope of the SMARTsurg framework.

The Universal Declaration of Human Rights

The Universal Declaration of Human Rights stipulates that:

> *"the recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world"*

Member States pledge to uphold universal respect for and observance of human rights as described by 30 articles to the Declaration. These fundamental rights apply to all human endeavours and the SMARTsurg project is, of course, no exception. However, the activities to be carried out in SMARTsurg presents no particular threat above and beyond any other workplace environment with respect to the rights defined by the Declaration. The specific articles of the Declaration will not, therefore, be described here in detail. Further information can be found at the United Nations Webpage http://www.un.org/en/documents/udhr/

The Convention 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data

Chapter I-Article 1

The purpose of this convention is to secure in the territory of each Party for every individual, whatever his nationality or residence, respect for his rights and fundamental freedoms, and in particular his right to privacy, with regard to automatic processing of personal data relating to him ("data protection").

Chapter I - Article 2

For the purposes of this convention:

(a) "personal data" means any information relating to an identified or identifiable individual ("data subject");
(b) "automated data file" means any set of data undergoing automatic processing;
(c) "automatic processing" includes the following operations if carried out in whole or in part by automated means: storage of data, carrying out of logical and/or arithmetical operations on those data, their alteration, erasure, retrieval or dissemination;
(d) "controller of the file" means the natural or legal person, public authority, agency or any other body who is competent according to the national law to decide what should be the purpose of the automated data file, which categories of personal data should be stored and which operations should be applied to them.

Chapter II – Article 5

Personal data undergoing automatic processing shall be:

(a) obtained and processed fairly and lawfully;
(b) stored for specified and legitimate purposes and not used in a way incompatible with those purposes;
(c) adequate, relevant and not excessive in relation to the purposes for which they are stored;
(d) accurate and, where necessary, kept up to date;
(e) preserved in a form which permits identification of the data subjects for no longer than is required for the purpose for which those data are stored.

Chapter II – Article 7

Appropriate security measures shall be taken for the protection of personal data stored in automated data files against accidental or unauthorized destruction or accidental loss as well as against unauthorized access, alteration or dissemination.

Chapter III – Article 12

1. The following provisions shall apply to the transfer across national borders, by whatever medium, of personal data undergoing automatic processing or collected with a view to their being automatically processed.
2. A Party shall not, for the sole purpose of the protection of privacy, prohibit or subject to special authorisation transborder flows of personal data going to the territory of another Party
3. Nevertheless, each Party shall be entitled to derogate from the provisions of paragraph 2:
    a) insofar as its legislation includes specific regulations for certain categories of personal data or of automated personal data files, because of the nature of those data or those files, except where the regulations of the other Party provide an equivalent protection;
    b) when the transfer is made from its territory to the territory of a non-Contracting State through the intermediary of the territory of another Party, in order to avoid such transfers resulting in circumvention of the legislation of the Party referred to at the beginning of this paragraph.

Further information can be found at the European Council Webpage http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm

Directive 95/46/EC (amendment 2002/58/EC) – EU

Chapter II – Section I – Article 6

Member States shall provide that personal data must be:

(a) processed fairly and lawfully;

(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;

(c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;

(d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified;

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use.

Chapter II – Section II – Article 7

Member States shall provide that personal data may be processed only if:

(a) the data subject has unambiguously given his consent; or

(b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; or

(c) processing is necessary for compliance with a legal obligation to which the controller is subject; or

(d) processing is necessary in order to protect the vital interests of the data subject; or

(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed; or

(f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under Article 1.

Chapter II – Section IV Article 10

Information in cases of collection of data from the data subject

Member States shall provide that the controller or his representative must provide a data subject from whom data relating to himself are collected with at least the following information, except where he already has it:

1. the identity of the controller and of his representative, if any;
2. the purposes of the processing for which the data are intended;
3. any further information such as:
   - the recipients or categories of recipients of the data,
   - whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply,
   - the existence of the right of access to and the right to rectify the data concerning him in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.

Chapter II – Section IV Article 11

Information where the data have not been obtained from the data subject

1. Where the data have not been obtained from the data subject, Member States shall provide that the controller or his representative must at the time of undertaking the recording of personal data, or if a disclosure to a third party is envisaged, no later than the time when the data are first disclosed, provide the data subject with at least the following information, except where he already has it:
   (a) the identity of the controller and of his representative, if any;
   (b) the purposes of the processing;
   (c) any further information such as
      - the categories of data concerned;
      - the recipients or categories of recipients;
      - the existence of the right of access to and the right to rectify the data concerning him in so far as such further information is necessary, having regard to the specific circumstances in which the data are processed, to guarantee fair processing in respect of the data subject.
2. Paragraph 1 shall not apply where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of such information proves impossible or would involve a disproportionate effort or if recording or disclosure is expressly laid down by law. In these cases Member States shall provide appropriate safeguards.

Chapter II – Section V Article 12

Member States shall guarantee every data subject the right to obtain from the controller:

(a) without constraint at reasonable intervals and without excessive delay or expense:
   - confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data

concerned, and the recipients or categories of recipients to whom the data are disclosed;

- communication to him in an intelligible form of the data undergoing processing and of any available information as to their source;
- knowledge of the logic involved in any automatic processing of data concerning him at least in the case of the automated decisions referred to in Article 15 (1);

(b) as appropriate the rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Directive, in particular because of the incomplete or inaccurate nature of the data;

(c) notification to third parties to whom the data have been disclosed of any rectification, erasure or blocking carried out in compliance with (b), unless this proves impossible or involves a disproportionate effort.

Chapter II – Section VII Article 14

Member States shall grant the data subject the right:

(a) at least in the cases referred to in Article 7 (e) and (f), to object at any time on compelling legitimate grounds relating to his particular situation to the processing of data relating to him, save where otherwise provided by national legislation. Where there is a justified objection, the processing instigated by the controller may no longer involve those data;

(b) to object, on request and free of charge, to the processing of personal data relating to him which the controller anticipates being processed for the purposes of direct marketing, or to be informed before personal data are disclosed for the first time to third parties or used on their behalf for the purposes of direct marketing, and to be expressly offered the right to object free of charge to such disclosures or uses.

Member States shall take the necessary measures to ensure that data subjects are aware of the existence of the right referred to in the first subparagraph of (b).

Chapter II – Section VIII Article 16

Any person acting under the authority of the controller or of the processor, including the processor himself, who has access to personal data must not process them except on instructions from the controller, unless he is required to do so by law.

Chapter II – Section VIII Article 17

1. Member States shall provide that the controller must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

   Having regard to the state of the art and the cost of their implementation, such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected.

2. The Member States shall provide that the controller must, where processing is carried out on his behalf, choose a processor providing sufficient guarantees in respect of the

technical security measures and organizational measures governing the processing to be carried out, and must ensure compliance with those measures.

3. The carrying out of processing by way of a processor must be governed by a contract or legal act binding the processor to the controller and stipulating in particular that:
   - the processor shall act only on instructions from the controller,
   - the obligations set out in paragraph 1, as defined by the law of the Member State in which the processor is established, shall also be incumbent on the processor.
4. For the purposes of keeping proof, the parts of the contract or the legal act relating to data protection and the requirements relating to the measures referred to in paragraph 1 shall be in writing or in another equivalent form.

Further information can be found at the European Commission Webpage (http://ec.europa.eu/justice/data-protection/index_en.htm).

The Declaration of Helsinki on research involving human subjects

B.11

It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

B.14

The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

B.18

Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

B.19

Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

B.20

Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

B.21

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

B.22

Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

B.23

Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.

B.24

In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

B.30

Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C.33

At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

C.34

The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.

Further information can be found at the World Medical Association Webpage (http://www.wma.net/en/30publications/10policies/b3/).

The UK Data Protection Act

7 Right of access to personal data.

(1)Subject to the following provisions of this section and to [F1sections 8, 9 and 9A], an individual is entitled—

(a) to be informed by any data controller whether personal data of which that individual is the data subject are being processed by or on behalf of that data controller,

(b) if that is the case, to be given by the data controller a description of—

(i)the personal data of which that individual is the data subject,

(ii)the purposes for which they are being or are to be processed, and

(iii)the recipients or classes of recipients to whom they are or may be disclosed,

(c) to have communicated to him in an intelligible form—

(i)the information constituting any personal data of which that individual is the data subject, and

(ii)any information available to the data controller as to the source of those data.

10 Right to prevent processing likely to cause damage or distress.

(1)Subject to subsection (2), an individual is entitled at any time by notice in writing to a data controller to require the data controller at the end of such period as is reasonable in the circumstances to cease, or not to begin, processing, or processing for a specified purpose or in a specified manner, any personal data in respect of which he is the data subject, on the ground that, for specified reasons—

(a)the processing of those data or their processing for that purpose or in that manner is causing or is likely to cause substantial damage or substantial distress to him or to another, and

(b)that damage or distress is or would be unwarranted.

11 Right to prevent processing for purposes of direct marketing.

(1) An individual is entitled at any time by notice in writing to a data controller to require the data controller at the end of such period as is reasonable in the circumstances to cease, or not to begin, processing for the purposes of direct marketing personal data in respect of which he is the data subject.

The Data Protection Code - Legislative Decree no. 196/2003 (Italian law)

Sections

PART 1 – GENERAL PROVISIONS

TITLE I – GENERAL PRINCIPLES

TITLE II – DATA SUBJECT'S RIGHTS

TITLE III – GENERAL DATA PROCESSING RULES

TITLE IV – ENTITIES PERFORMING PROCESSING OPERATIONS

TITLE V – DATA AND SYSTEM SECURITYTITLE

TITLE VII – TRANSBORDER DATA FLOWS

For further information please visit the following website:

http://194.242.234.211/documents/10160/2012405/Personal+Data+Protection+Code+-+Legislat.+Decree+no.196+of+30+June+2003.pdf

Greek Law 2472/1997: Protection of Individuals with regard to the Processing of Personal Data

Chapter B-Article 4

1. Personal data, in order to be lawfully processed, must be:
   a) collected fairly and lawfully for specific, explicit and legitimate purposes and fairly and lawfully processed in view of such purposes.
   b) adequate, relevant and not excessive in relation to the purposes for which they are processed at any given time.
   c) accurate and, where necessary, kept up to date.
   d) kept in a form which permits identification of data subjects for no longer than the period required, according to the Authority, for the purposes for which such data were collected or processed. Once this period of time is lapsed, the Authority may, by means of a reasoned decision, allow the maintenance of personal data for historical, scientific or statistical purposes, provided that it considers that the rights of the data subjects or even third parties are not violated in any given case.
2. It shall be for the Controller to ensure compliance with the provisions of the previous paragraph. Personal data, which have been collected or are being processed in breach of the previous paragraph, shall be destroyed, such destruction being the Controller's responsibility. The Authority, once such a breach is established, either ex officio or upon submission of a relevant complaint, shall order any such collection or processing ceased and the destruction of the personal data already collected or processed.

Chapter B-Article 5

1) Processing of personal data will be permitted only when the data subject has given his/her consent.
2) Exceptionally, data may be processed even without such consent, only if:

a) processing is necessary for the execution of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract.

b) processing is necessary for the compliance with a legal obligation to which the Controller is subject.

c) processing is necessary in order to protect the vital interests of the data subject, if s/he is physically or legally incapable of giving his/her consent.

d) processing is necessary for the performance of a task carried out in the public interest or a project carried out in the exercise of public function by a public authority or assigned by it to the Controller or a third party to whom such data are communicated.

e) processing is absolutely necessary for the purposes of a legitimate interest pursued by the Controller or a third party or third parties to whom the data are communicated and on condition that such a legitimate interest evidently prevails over the rights and interests of the persons to whom the data refer and that their fundamental freedoms are not affected.

3. The Authority may issue special data processing rules for the more usual categories of data processing and files, which do not evidently affect the rights and freedoms of the persons to whom such data refer. These categories will be specified

Chapter B-Article 10

1. The processing of personal data shall be confidential. It shall be carried out solely and exclusively by persons acting under the authority of the Controller or the Processor and upon his/her instructions. 2. In order to carry out data processing the Controller must choose persons with corresponding professional qualifications providing sufficient guarantees in respect of technical expertise and personal integrity to ensure such confidentiality.

3. The Controller must implement appropriate organisational and technical measures to secure data and protect them against accidental or unlawful destruction, accidental loss, alteration, unauthorised disclosure or access as well as any other form of unlawful processing. Such measures must ensure a level of security appropriate to the risks presented by processing and the nature of the data subject to processing. Without prejudice to other provisions, the Authority shall offer instructions and issue regulations in accordance with article 19 paragraph 1 k involving the level of security of data and of the computer and information infrastructure, the security measures that are required for each category and processing of data as well as the use of privacy-enhancing technologies.

4. If the data processing is carried out on behalf of the Controller, by a person not dependent upon him, the relevant assignment must necessarily be in writing. Such assignment must necessarily provide that the Processor carries out such data processing only on instructions from the Controller and that all other obligations arising from this article shall mutatis mutandis be borne by him.

Chapter C-Article 12

1. Everyone is entitled to know whether personal data relating to him are being processed or have been processed. As to this the Controller must answer in writing. 2. The data subject shall be entitled to request and obtain from the Controller, without undue delay and in an intelligible and express manner, the following information:

a) All the personal data relating to him as well as their source.

b) The purposes of data processing, the recipient or the categories of recipients.

c) Any developments as to such processing for the period since s/he was last notified or advised.

d) The logic involved in the automated data processing.

e) The correction, deletion or locking of data, the processing of which is not in accordance with the provisions of the present law, especially due to the incomplete or inaccurate nature of data

f) The notification to third parties, to whom the data have been announced, of any correction, deletion or locking which is carried out in accordance with case

e), taken that the notification is not impossible or does not demand disproportionate efforts.

3. The right referred to in the preceding paragraph and the rights arising from article 13 are exercised by means of a relevant application to the Controller and the simultaneous payment of an amount of money, the amount of which, the method of payment as well as any other relevant matter will be regulated by a decision of the Authority. This amount will be returned to the applicant if his/her request to rectify or delete data is considered valid by the processor or the Authority, in case of an appeal before it. The Controller must in this case provide the applicant without undue delay, free of charge and in an intelligible form, a copy of the rectified part of the data relating to him.
4. Should the Controller not reply within a period of fifteen (15) days or should his/her answer be unsatisfactory, the data subject shall be entitled to appeal before the Authority. In the event the Controller refuses to satisfy the request of the party concerned, s/he must notify the Authority as to his/her response and inform the party concerned as to his/her right of appeal before it.
5. By virtue of a decision by the Authority, upon application by the Controller, the obligation to inform, pursuant to paragraphs 1 and 2 of the present article, may be lifted in whole or in part, provided that the processing of personal data is carried out on national security grounds or for the detection of particularly serious crimes. In this case the President of the Authority or his/her substitute carries out all necessary acts and has free access to the files.
6. Data pertaining to health matters will be communicated to the data subject by means of a medical doctor.

More information can be found in the Hellenic Data Protection Authority official site http://www.dpa.gr/portal/page?_pageid=33,43560&_dad=portal&_schema=PORTAL .

Greek Law 3471/2006: Protection of personal data and privacy in the electronic telecommunications sector and amendment of law 2472/1997

Chapter 1-Article 4

1. Any use of electronic communications services offered through a publicly available electronic communications network, as well as the pertinent traffic and location data, as described in art. 2 of the present law, shall be protected by the principle of confidentiality of telecommunications. The withdrawal of confidentiality shall be allowed only under the procedures and conditions provided for in Art. 19 of the Constitution.
2. Listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic and location data is prohibited, except when legally authorised.
3. The legally authorised recording of communications and the related traffic data is allowed when carried out in the course of lawful business practice for the purpose of providing evidence of a commercial transaction or of any other business communication, under the condition that both parties have provided their consent in writing, upon previous notification as to the aim of the recording. An act by the Personal Data Protection Authority defines the manner in which parties are notified and provide consent, as well as the manner and duration of storage for the recorded conversations and relevant traffic data.
4. With the reservation of complying with the obligations arising from the protection of confidentiality, according to the present law, technical storage is allowed, where necessary for the conveyance of the transmission.
5. The storage of data or gaining access to information already stored in the terminal equipment of a subscriber or user is only allowed if the specific subscriber or user has given his/her consent following clear and detailed information, according to art. 11, par. 1 of law 2472/1997, as effective. The consent of the subscriber or user can be given by means of appropriate settings in the web browser or by means of another application. The aforementioned shall not impede any technical storage or access, the sole purpose of which is the conveyance of information through an electronic communications network, or which is necessary for the provision of information society services explicitly requested by the user or subscriber. An act by the Personal Data Protection Authority analytically defines the manner in which information is provided and consent is declared.

Chapter 1-Article 12

1. The provider of a publicly available electronic communications service must take appropriate technical and organisational measures to safeguard security of its services and the security of the public electronic communications network. These measures, if necessary, shall be taken jointly with the provider of public electronic communications services and shall ensure a level of security appropriate to the risk presented, taking into account state of the art technical capabilities and the cost of their application.
2. In case of a particular risk of a breach of the network's security, the provider of a publicly available electronic communications service must inform the subscribers. If the risk lies outside the scope of the measures to be taken by the service provider, they must also inform the subscribers of any possible remedies, including an indication of the likely costs involved.
3. Subject to article 10 of law 2472/1997, as effective, by the measures of the present article at least: a) it is ensured that only authorized personnel and for lawfully approved purposes shall have access to personal data, b) the stored or transferred personal data are protected against accidental or unlawful destruction, accidental loss or alteration and unauthorized or unlawful processing, including storage, access or disclosure and c) the application of security policy in relation to the processing of personal data is safeguarded. Relevant special provisions and regulations of Independent Authorities continue to apply.
4. The competent authorities issue recommendations for best practices about the security level that must be reached with the measures of the previous paragraphs.
5. In case of a personal data breach, the provider of publicly available electronic communications services notifies ADAE and DPA of the breach without undue delay. The notification to the competent authorities includes at least a description of the nature of the personal data breach and the contact points from which further information can be obtained. Moreover, the consequences of the breach are described and the measures that were suggested or taken by the provider to deal with the breach.
6. When the personal data breach may have unpropitious consequences to the personal data or the private life of the subscriber or other person, the provider notifies without undue delay the affected subscriber or the affected person. The notification of the previous section includes at least description of the nature of the personal data breach and the contact points from which further information can be obtained as well as recommendations that can limit potential unfavourable results from the personal data breach.
7. The notification of the affected subscriber or affected person of the personal data breach is not necessary if the provider has proved to the competent authorities in a satisfactory manner that he/she has applied the appropriate technical security measures and that these measures were applied for the data related to the security breach. These measures for technological protection must at least include secure data encryption so that unauthorized access is not possible. If the provider has not provided notification, according to paragraph 6 of present article, the competent authorities after examining the possible unpropitious consequences from the breach can ask him/her to do so.
8. With a joint act DPA and ADAE can issue guidelines on the circumstances under which the notification of the personal data breach is required from the provider, the format of this notification and the way according to which this notification must be done.
9. The providers that provide publicly available electronic communications services keep a file with personal data breaches that includes the description of relevant incidents, their results, corrective actions which they undertook, with sufficient data so that the competent authorities will be able to verify that they have complied with the provisions of the present article. This file includes only information that is necessary for this purpose.
10. For the handling of the personal data breaches pursuant to the provisions of the present article, the competent authorities notify each other mutually for the measures that they intend to take.
11. The processing of the users' and subscribers' personal data, as well as the relevant traffic, location and billing data, must be assigned to persons acting under the authority of providers of the public communications networks and publicly available electronic communications services, handling billing

or traffic management, customer enquiries, fraud detection, marketing of the provider's electronic communications services or the provision of a value added service, and must be restricted to what is necessary for the purposes of such activities.
More information can be found in the Hellenic Data Protection Authority official site http://www.dpa.gr/portal/page?_pageid=33,43560&_dad=portal&_schema=PORTAL .

2.2.2 Establishment of Ethics Helpdesk

The Ethics Helpdesk was established in Month 1 of the project and will be active for the entire lifetime. It constitutes a centralized service that provides constant advice regarding ethical and data protection issues that may arise during the project's lifetime, while addressing any legal, privacy and ethical issues regarding the technologies developed by the consortium and providing its valuable input and responses as part of the Milestone 1. The Ethics Helpdesk is also in charge of ensuring that all partners provide the necessary participation in SMARTsurg as well as to the pilot-study participants. More information regarding the Ethics Helpdesk can be found in the Deliverable 1.1 ("Project Reference Manual and Quality Assessment Plan") of the SMARTsurg project.

For the successful diffusion and establishment of the ethical guidelines, a preliminary Ethics and Safety Manual is provided in section 4.2 of this document, which provides all the necessary information and guidelines for the topics addressed by the SMARTsurg framework.

2.2.3 Internal Reports

In order to identify all the possible ethical risks and issues that may arise during the project lifetime, a series of internal brief reports will be sent to all partners for facilitating ongoing monitoring of changes, actions taken as well as for receiving feedback regarding any new directives that should be taken into account. In that way all partners will be kept up to date regarding the Ethics of the SMARTsurg project and will be encouraged and helped to create a solid ethical framework. The exchange of internal reports as well as the actions taken in the following will be decided by the partner responsible.

2.2.4 Documentation and Summary of the results

The results of the previous steps are analysed in the current deliverable. In addition, as the pilot study sites and the demonstration sites involve the participation of adult healthy volunteers and in several cases data collection takes place, a preliminary Ethics and Safety Manual (provided in Section 4) has been delivered, summarizing all the guidelines that were considered.

3. Safety

Allowing for surgeons and robots to cooperate and interact close to one another can lead to effective human-robot teams. Next generation robots are expected to interact in a more direct way with people, therefore, the topic of physical Human-Robot Interaction (pHRI) constitutes a challenging issue [[3], [4]], as in pHRI robots and humans tend to come in touch with one another, while sharing the same workspace, cooperating and exchanging forces. Consequently, ensuring security and safety for the human factor rises to be a matter of great significance. For succeeding this, such robots need to be designed and operated with respect to certain requirements. In the context of SMARTsurg, it is not only the teleoperated robot that operates in close proximity to humans, but also the robot holding the endoscopic camera, which may be physically guided by the assistant surgeon, in a collaborative fashion.

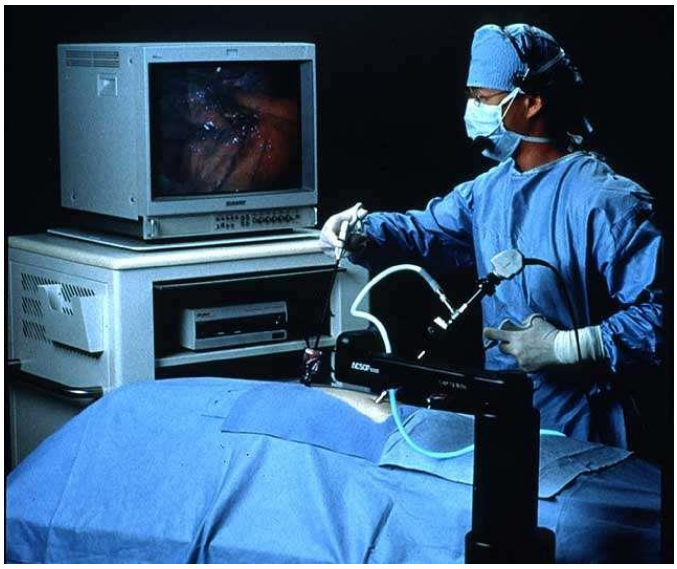

Figure 2: Human-Robot Interaction & Collaboration during surgery. (Source: https://www.spineuniverse.com/exams-tests/devices/robotics-computers-minimally-invasive-spine-surgery)

3.1 Safety in Collaborative Robots

Collaboration robots are used for tasks that require human-robot interaction and cooperation. According to *ISO 10218-1:2011*, collaborative operation is defined as *"the state in which purposely designed robots work in direct cooperation with a human within a defined workspace".* This takes place in the shared workspace which is precisely defined. For such robots, four basic principles exists for ensuring protection of the humans involved, which are described in details in the *EN ISO 10218 Standard, "Robots and robotic devices-Safety requirements for industrial robots", Part 1(Robots) & 2(Robot systems and integration)* as well

as in *ISO/DTS 15066,* "*Safety Requirements for industrial robots-Collaborative Operation" Standard*. These principles are listed below:

1. *Safety-rated monitored stop:* Refers to stopping the robot when a human enters in the collaborative workspace to continue when he/she has left the collaborative workspace. One way to accomplish this is through the placement of sensors for detecting human presence.
2. *Hand guiding:* This allows for a person to control the robot's motion, in order for the co-workers to be adequately protected, even when the robot is powered.
3. *Speed and Separation monitoring:* This way, the robot's movement can be adjusted according to the human location. The robot gradually decreases its speed when a human enters the collaborative are to finally stop if the person comes too close.
4. *Power and Force limiting:* Refers to the process of limiting the robot's force for avoiding to harm the co-workers. A variety of mechanisms and methods are available for achieving this.

In the following sections, a brief description of the collaborative robots considered for the SMARTsurg purposes is provided, with special attention given to their features and characteristics that ensure human safety.

3.2 The YuMi (ABB IRB 14000) Robot

For the purposes of the SMARTsurg project, the friendly collaborative robot, YuMi [5], is considered, mainly for the manipulation of the endoscope camera by the assistant surgeon. The YuMi robot constitutes an innovative human-friendly dual arm robot that requires breakthrough functionality that was designed in order to boost automation potential in the global robot industry. Safety constitutes one of the basic characteristics of this robot, allowing it to remove barriers to human-robot interaction and collaboration, while removing the need for fences and cages. As a dual arm robot, YuMi requires dexterous grippers, accurate vision and sensitive force control feedback as well as flexible software and built-in safety features.

Figure 3: YuMi robot and human-robot interaction (Source: http://new.abb.com/products/robotics/yumi, http://www.abb.com/cawp/seitp202/c9aa2ac92a152904c125801200537df0.aspx)

These properties enable programming through teaching instead of coding. An additional characteristic of this robot, is the fact that it features human dimensions, while its dual-arms have seven degrees of freedom providing human-like dexterity to the robot. YuMi's weight is only 35 kg. It has an integrated control system as well as integrated internal cabling for multiple input/output commands including air and digital. It is highly portable and re-deployable, using standard household electrical power.

Safety in YuMi Robot

Safety is a core element of the YuMi robot [6]. YuMi has a skeleton that is covered by floating plastic casing that is wrapped in soft padding for absorbing significant forces of unforeseen impacts. Even though it is made of rigid magnesium, it still remains lightweight, thus limiting the energy of any unforeseen impacts. Moreover, YuMi does not have any pinch points, similar to the human arm, preventing in this way the crushing of sensitive ancillary parts between two opposing surfaces as the axes open and close.

One of YuMi's important features that highly increases safety during human-robot interaction and collaboration constitutes its ability to pause its motion within only milliseconds when it senses an impending, unexpected impact (e.g. collision with a co-worker, etc.), and afterwards restart its operation easily. Additionally,

Even though YuMi's design focuses on safety, this robot does not lack on precisio and speed. Indeed, it is able to move at a maximum velocity of 1,500 mm/sec while returning to the same point with the high accuracy of 0.02 mm.

Figure 4: YuMi robot and human-robot interaction (Source: http://www02.abb.com/global/seitp/seitp202.nsf/0/93444951d1557c59c1257e200051d731/$file/YuMi.jpg).

YuMi's safety characteristics can be summarized as follows:

1. Inherently safe system of automated small parts assembly;
2. Automation with minimized safety risks;
3. Safety padding for absorbing forces;
4. Ability to immediately sense collisions and identify changes;
5. Ability to pause its motion within milliseconds if necessary for avoiding injuries;
6. Absence of pinch points;
7. It consists of lightweight and soft materials;
8. Monitoring tools (e.g. anonymous tracking of people by visual and thermal cameras) are added as tools preventing incidents.

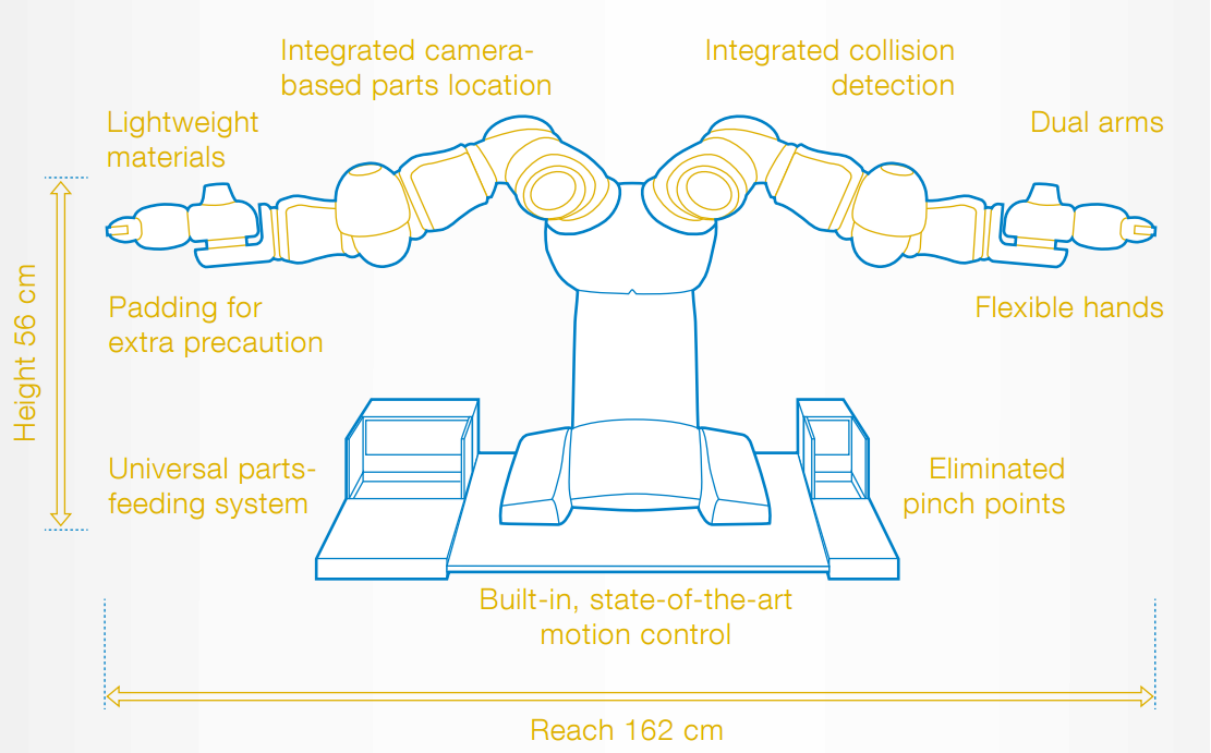

Figure 5: YuMi's safety characteristics

YuMi is safety certified. This means that there is no need for the owner to certify the robot, as it is already certified by an Independent Body. Additionally, this robot is in place to handle static sensitive parts (ISD Protection).

3.3 The KUKA LWR4+ Robotic Arm

Another robot considered for the project purposes is KUKA LWR4+ [8]. This robot was designed to simulate the functional characteristics of the human arm. This robotic arm is therefore ideal for a wide range of applications regarding physical human-robot interaction (pHRI).

KUKA LWR4+ is entirely made of aluminum and contains all necessary components (motors, wires, sensors, etc.) in its enclosed housing. It features seven degrees of freedom allowing for greater precision and flexibility as well as for improved maneuverability and accessibility. Its payload capacity is 7 kg whereas its weight is only about 16 kg, making the robot portable. Additionally, this robotic arm is user-friendly and can be guided by hand throughout its work envelope. Moreover, due to its integrated torque sensor technology, it is extremely sensitive and responsive, while its rounded shape does not contain any sharp edges that may harm its co-workers. As a collaborative robot, its sensors detect external forces made by an obstacle or a human. These sensors are also independent from each other. These characteristics make the LWR a safe working partner, either for feeding human workers pieces or holding them while your employees work on it. Consequently, this robot constitutes a suitable solution for complex assembly tasks as well as for applications requiring direct human-robot interaction.

Figure 6: The KUKA LWR4+ robotic arm

3.4 KUKA LBR iiwa

The LBR iiwa is the world's first series-produced sensitive, and therefore HRC-compatible, robot. LBR stands for "Leichtbauroboter" (German for lightweight robot), iiwa for "intelligent industrial work assistant". For the first time, humans and robots can work together on highly sensitive tasks in close cooperation. The collaborative and sensitive LBR iiwa robot has payload capacities of 14 kilograms.

Thanks to its joint torque sensors, the LBR iiwa can detect contact immediately and reduces its level of force and speed instantly. Its position and compliance control enables it to handle delicate components without creating crushing and shearing hazards.

The lightweight LBR iiwa with its high-performance servo control is able to detect contours quickly under force control. It establishes the correct installation position and mounts components quickly and with the utmost precision with an axis-specific torque accuracy of ±2% of the maximum torque. The LBR iiwa can also find small, delicate components in next to no time without your assistance. In the context of SMARTsurg it is considered to be employed for the manipulation of the surgical tools serving as the slave arms of the teleoperating system.

Figure 7: The KUKA LBR iiwaR820 robotic arm

4. Ethics and Safety Manual

4.1 The Scope of the Ethics and Safety Manual

The current Ethics and Safety Manual has been produced by CERTH towards the diffusion and establishment of all the ethical guidelines that have to be taken into consideration during the pilot studies and demonstrations, where volunteer participants will be involved and data collection will be carried out. This Ethics and Safety Manual has been composed, including all the necessary ethical and privacy guidelines, in order to inform all involved parties towards 1) preserving the privacy of the users, 2) ensuring their safety and 3) respecting their rights as volunteer test subjects.

This document is intended, first of all, for all project staff that will participate in the preparation and realization of pilot studies. Software developers, managerial and technical staff members of the partners should carry all their activities in accordance with the guidelines outlined here. Furthermore, the manual is directed to all people involved in the project and especially to the volunteer participants who are the ones actually participating in the pilot studies, who may wish to be further informed about the guidelines adopted by the project.

The manual will be constantly updated throughout the project's lifetime based on any new ethical or safety issues that may arise. The final version of the Ethics and Safety Manual will be available on month 36, and will provide all the necessary information and guidelines for the topics addressed by the SMARTsurg framework.

4.2 Privacy and Data Protection

European regulations about acquiring personal data are quite explicit, as seen in Section 2. Of particular interest for the SMARTsurg project is the use of normal and infrared cameras to automatically monitor the robot's workspace. Such automatic acquisition of data could occur without the full knowledge of a participant or observer. And even when the person is aware that data is being acquired, care must be taken to ensure that the acquired data is not used in a inappropriate manner. With these concerns in mind the following guidelines are issued for the SMARTsurg project:

- No data shall be collected without the explicit informed consent of the individuals under observation. This involves being open with participants about what they are involving themselves in and ensuring that they have agreed fully to the procedures/research being undertaken by giving their explicit consent;
- No data collected should be sold or used for any purposes other than the current project;
- A data minimization policy should be adopted at all levels of the project and should be supervised by the respective ethical/privacy helpdesk of the project. This will ensure that no data which is not strictly necessary to the completion of the current study will be collected;

- Any ancillary personal data obtained during the course of the research should be immediately deleted. However, this kind of ancillary data should be minimized as much as possible in any case.
- Special attention should also be paid to complying with the Council of Europe's Recommendation R(87)15 on the processing of personal data for police purposes, Art.2:
- "*The collection of data on individuals solely on the basis that they have a particular racial origin, particular religious convictions, sexual behavior or political opinions or belong to particular movements or organizations which are not proscribed by law should be prohibited. The collection of data concerning these factors may only be carried out if absolutely necessary for the purposes of a particular inquiry*". If employees of partner organizations (e.g UWE employees) , or university students serving in any partner university, are to be recruited, specific measures should be in place in order to protect them from a breach of privacy/confidentiality and any potential discrimination. In particular their names should not be made public and their participation should not be communicated to their managers.

4.3 Safety

The SMARTsurg project will ensure the safety of workers and volunteer participants throughout the research activities carried out. For experiments involving human-robot interactions, the following guidelines are recommended:

1. Safety-rated monitored stop shall be used in order to enable the robot to pause when a human enters in the collaborative workspace and to afterwards continue when he/she has left the collaborative workspace. The robot shall also be equipped with an emergency shut-off button accessible to both the experiment operator and the volunteer test subject (if present).
2. Hand guiding shall be used for allowing a person to control the robot's motion.
3. Speed and Separation monitoring shall be used for facilitating the adjustment of the robot's movement according to the human location.
4. Power and Force limiting shall be used for enabling the limitation of the robot's force in order to avoid harming the co-workers.
5. Sensors shall be installed in the robot to avoid collisions with humans.
6. External monitoring tools (e.g people-tracking by visual cameras)[1] shall be installed where feasible to monitor the workspace and ensure co-workers' safety.
7. The robot shall be able to sense workspace changes that could result in unintended or harmful collisions.
8. The robot shall be made from soft and light materials for minimizing harm if collision occurs.
9. Safety padding shall be used for absorbing forces in case of unexpected impact.

[1] To conform to guidelines on data protection, any such tracking of persons shall be recorded in a completely anonymous fashion.

10. The robot should not have pinch points.

For experiments involving the measurement of human physiological parameters:

1. Measurements of human movements and physiological parameters (such as muscle activations and reflex activities during the execution of assembly tasks) shall be performed in a ***non-invasive*** manner (i.e. no physical devices shall be inserted into the body and no electrical currents, radiations or magnetic fields shall be applied).
2. Experiments shall be designed to pose little or no risk to the volunteers who will participate as operators or assistants of the SMARTsug system.

In all cases, the work environment shall be subject to review by the local safety authorities and clear instructions about general and specific safe working practices shall be posted in easily visible manner at each workstation. When the assurance of safe operation of electromechanical equipment requires a minimal level of training and expertise, each partner entity shall put in place formal procedures to certify individual operators of that equipment.

4.4 Protection of Volunteer Participants

The SMARTsurg consortium is fully aware of the ethics implications arising from the proposed SMARTsurg activities, particularly with regards to volunteer participants who will take part in pilot studies and final evaluation of the SMARTsurg technologies.

The SMARTsurg consortium takes note of the Helsinki Declaration on Research Involving Human Subjects. These accords were developed in response to abuses in the biomedical and scientific communities that occurred in the 1950 and 1960's in which the health and psychological well-being of volunteer subjects were jeopardized without the full knowledge and consent of the volunteer subjects. The Helsinki accords prescribe a number of measures that should be put in place to protect the rights of the subjects in these kinds of experiments. The applicability of the Helsinki accords in the context of SMARTsurg is, however, somewhat ambiguous because the experiments to be performed here are not, 'biomedical' in nature, since phantoms, or animal cadavers will be used as surrogates of the actual patients. Strict adherence to the Helsinki accords is therefore not required and would impose an unnecessary burden on the research teams. This is particularly true for the "independent review board" that the Helsinki accords require for biomedical studies.

It is recommended, however, that the spirit of the Helsinki accords be respected so as to protect the rights of the volunteer surgeons in the experiments. Thus, the following guidelines are proposed:

1. All experiments shall be subject to an independent review for safety. In the case of experiments intended to measure the physiological processes in humans, it is recommended that the research be submitted to an independent review board as defined by the Helsinki accords. When the experiments concern evaluation of a robotic system interacting with a human user, then review by the partner's internal safety authority will be considered sufficient.
2. Participants must be healthy adults legally able to give informed consent, which is evident since we are referring to medical practitioners, such as surgeons and their assistants.
3. Participation will be strictly voluntary. Participants will be free to withdraw their consent at any time, without repercussions.

4. Care must be taken that employees of the SMARTsurg beneficiaries will not be obligated to participate as a condition of their employment nor will the data from the experiments be used in any way to condition an individual's career advancement within the organization. Employees of the SMARTsurg beneficiaries shall be notified, as part of the informed consent process, about redress options within their organization that can be pursued if they feel that their rights have been abridged in this regard.
5. To protect privacy, data will be recorded in a fully anonymous fashion, whenever possible, with no information that might be used to link the data to a given individual. When data from the same participant must be correlated across several test sessions, the data shall be stored with a randomly generated code. Only the immediate research team will know the identity of the volunteers and the codes will be made available to investigator team on a strict need-to-know basis. The names of individuals will not be released without the written consent of the participant, unless required by law.
6. Participants may be compensated for their participation. Employees who participate as part of their normal work hours will receive no other compensation. Other volunteers may be compensated their time, but special attention will be paid to avoid any form of unfair inducement.
7. Potential subjects will be provided with a written document that describes the physical risks associated with their participation and the steps taken to mitigate the risks. The written document must also describe the safety procedures that volunteer subjects are required to follow to avoid injury and the document must outline the participant's rights and responsibilities.
8. Individual volunteer subjects will participate only after giving written informed consent. A model of the informed consent form is given in **Annex II** of the present document. Volunteer subjects must be given ample opportunity to request further information about the procedures and risks both before and after signing the consent form.

5. Conclusions

This document aims to define the basic ethical and safety guidelines to be followed throughout the SMARTsurg project's lifecycle. Therefore, a thorough analysis of the European, national and international legislations and directives regarding data privacy and security is accomplished, while the basic standards and features regarding safety in collaboration robots considered for the manipulation of the endoscope, are also presented. In this direction, a brief summary of the robots (YuMi, KUKA LSR4+) used for the purposes of the project is provided, with special focus on their safety features. It is emphasized that this is a preliminary version of the project's Ethics and Safety Manual, and as a result, it constitutes an ongoing document that will evolve along with the progress of the project and will be updated on a regular basis, until its final version is provided though the activities of D1.2 "Ethics and Safety Manual for SMARTsurg technology", on the final month of the project duration.

References

[2] SMARTsurg Grant Agreement Annex I – "Description of Action" (DoA)
[3] Lasota, Przemyslaw A., Gregory F. Rossano, and Julie A. Shah. "Toward safe close-proximity human-robot interaction with standard industrial robots."*Automation Science and Engineering (CASE), 2014 IEEE International Conference on*. IEEE, 2014.
[4] SAFETY ISSUES FOR HUMAN–ROBOT COOPERATION IN MANUFACTURING SYSTEMS, Agostino De Santis, Bruno Siciliano, VRTest 2008
[5] http://new.abb.com/products/robotics/yumi
[6] https://library.e.abb.com/public/c24623eb22a427c4c1257e260020ad6c/new_ROB0318EN_YuMi_backgrounder.pdf?filename=new_ROB0318EN_YuMi_backgrounder.pdf
[7] https://library.e.abb.com/public/e58f8669ee5792e5c1257e2500419e00/IRB14000.pdf?filename=IRB14000.pdf
[8] http://www.kukaconnect.com/wp-content/uploads/2012/07/KUKA_LBR4plus_ENLISCH.pdf

Annex I: SMARTsurg Ethical Approval Form

Submitted to: Date Submitted:

Review Completed:

Researcher(s) Notified:

Application for Ethical Approval from

Name of investigator: *[provide name]* Email: *[provide e-mail address]*

Project Title: SMARTsurg, “SMart weArable Robotic Teleoperated surgery”

GENERAL DESCRIPTION OF THE PROJECT AND PURPOSE OF USE (BACKGROUND)

The SMARTsurg project aims at developing a. More specifically, this project aims to:

1. Develop a dexterous, adaptable anthropomorphic surgical instrument
2. Develop a framework for providing haptic feedback from the surgical instrument to the surgeon
3. Develop a strategies for dynamic active constraints construction and their guaranteed satisfaction.
4. Develop advanced cognition and perception abilities to achieve the real-time and on-the-fly reconstruction of the operation area
5. Validate SMARTsurg project results in realistic scenarios involving procedures on different surgical domains.

Through this accomplishment, SMARTsurg intends to.

[*Fill in the details of the procedure*]

ETHICS AND DEONTOLOGY

The SMARTsurg project has followed the appropriate privacy and security guidelines during the gathering of data from participants. These guidelines aim at preserving the privacy of the user, protecting his/her private data and limiting the risk of interception to a minimum. The integrity of the information is important for the project, and thus the following requirements have been fulfilled:

1. All experiments shall be subject to an independent review for safety. In the case of experiments intended to measure the physiological processes in humans, it is recommended that the research be submitted to an independent review board as defined by the Helsinki accords. When the experiments concern evaluation of a robotic

system interacting with a human user, then review by the partner's internal safety authority will be considered sufficient.

2. Participants must be healthy adults legally able to give informed consent. Children or members of other 'vulnerable' populations (patients, mentally challenged, elderly, etc.) will be excluded.
3. Participation will be strictly voluntary. Participants will be free to withdraw their consent at any time, without repercussions.
4. Care must be taken that employees of the SMARTsurg beneficiaries will not be obligated to participate as a condition of their employment nor will the data from the experiments be used in any way to condition an individual's career advancement within the organization. Employees of the SMARTsurg beneficiaries shall be notified, as part of the informed consent process, about redress options within their organization that can be pursued if they feel that their rights have been abridged in this regard.
5. To protect privacy, data will be recorded in a fully anonymous fashion, whenever possible, with no information that might be used to link the data to a given individual. When data from the same participant must be correlated across several test sessions, the data shall be stored with a randomly generated code. Only the immediate research team will know the identity of the volunteers and the codes will be made available to investigator team on a strict need-to-know basis. The names of individuals will not be released without the written consent of the participant, unless required by law.
6. Participants may be compensated for their participation. Employees who participate as part of their normal work hours will receive no other compensation. Other volunteers may be compensated their time, but special attention will be paid to avoid any form of unfair inducement.
7. Potential subjects will be provided with a written document that describes the physical risks associated with their participation and the steps taken to mitigate the risks. The written document must also describe the safety procedures that volunteer subjects are required to follow to avoid injury and the document must outline the participant's rights and responsibilities.

Summarizing based on the above it is concluded that the user integrity and his/her personal data protection are ensured within the SMARTsurg project with the best possible way.

I have read the policies regarding the use of human participants and agree to abide by them. I am also familiar with the ethical principles with regard to human participants and the data protection Act. I further agree to submit any significant changes in procedures or measurement instruments for additional review.

Signed:

Researcher

_____

Ethical Committee Member

_____

Annex II: Sample Participant's Consent Form

The EU Framework Programme for Research and Innovation HORIZON 2020

ICT-26-2016: System abilities, development and pilot installations

SMart we**A**rable **R**obotic **T**eleoperated **surg**ery

732515

Title	**Consent Form for the Participation to the SMARTsurg Pilot**
Authors	
Contributors	
Summary	**Consent Form to be signed by the subjects being recorded for pilots**

1.Purpose

The SMARTsurg project aims to develop an advanced system for performing R-A MIS, in order to reduce the surgeon's cognitive load related to the system's operation that will ultimately

allow shorter training time, while delivering increased accuracy, safety, reduced MIS procedure time, and expanded applicability. To this end, this project aims to design and develop a wearable interface for a surgical system using a) highly dexterous anthropomorphic surgical instruments b) wearable hand exoskeleton with haptic feedback for controlling the surgical instruments, and c) wearable smart glasses for augmented reality guidance of the surgeon based on real-time 3D reconstruction of the surgical field. High dependability will be achieved by utilising real-time dynamic active constraints to the instruments' motion, in order to restrict it to the safe regions. SMARTsurg developments will employ a user-centred approach for efficient technology adoption and commercialisation. This will be achieved using short prototyping and testing cycles supported by focused end-user and commercials requirements This study is part of a European research project called SMARTsurg (Smart wearable Robotic Teleoperated surgery) funded by the European Commission's Directorate-General for Research and Innovation (DG RTD), under its Horizon 2020 Research and Innovation programme (H2020).

2.Procedure

The SMARTsurg project, following the data protection principles concerning human rights, designed the following pilot applications to demonstrate. In particular the pilots refer to …

[*Experiment details to be filled in*]

The purpose of the above-mentioned scenarios is clearly experimental. They were designed to assess the technology and effectiveness of the solutions proposed by SMARTsurg.

3.Personal Data Handling

For the needs of the SMARTsurg project a set of [*define equipment use and the purpose served*].

[*Define people having access to personal data, the duration for which the data will be stored and the kind of data that will be gathered.*]

No personal data will be ever used for any purposes different from those stated in this form. Your personal data will not be transferred to any third party or even commercialized. You may exercise your rights of access, rectification and deletion of data at any time. In order to do so, you will need to communicate with the [*define person in charge*] by a letter addressed to:

[define person in charge]

[partner name]

[address]

[postal code, city, country]

or by e-mail to the following address: *[provide e-mail address]*

4.Confidentiality

The research team responsible for the data collection sessions will record the data collected in a file with randomly generated code. Only the immediate research team will know the identity of the volunteers and the data will be reported only in an anonymous fashion. Data files will be identified by a code known only to the investigator team and your name will not be released without your written consent, unless required by law. The results of the study could be published in books or magazines, however, your name will never be revealed in any document, publication or teaching materials.

5.Right to get more information about the study

You can ask any questions about the study at any time throughout the record. The principal researcher will be available to answer your questions, interests or concerns about the study. You will be informed of any new discovery that could occur throughout the study and that may affect your participation in future studies. If during the study and thereafter you wish to discuss your rights as a person who participates in an investigation, your participation in the study or your concerns about it, or if you do not want to continue in that investigation or future researches, please contact the principal researcher, at the address provided above (see section 3) any time you wish.

6.Refusal or cessation of participation

The participation in this *pilot application* is voluntary. You do not have to participate in the pilot study if you do not want to. If you choose to participate, you can change your mind or leave the study at any time without having to give explanations and without being yourself affected in any way. Similarly, at the discretion of the researcher responsible for the data collection sessions, you may be withdrawn from the study for any of the following reasons: (a) if the minimum requirements of the study are not met and (b) if for any reason the study is interrupted. It should be pointed out that agreeing to participate to the pilot application involves that you are agreed to attend in the programmed appointments, to fill all required questionnaires, to perform all required activities within the frame work of the study and to provide any asked information.

There will be no consequences for you in case you refuse to participate to the pilot application.

Under certain conditions your participation to the pilot application can be interrupted such as: You did not follow the research procedure as it was determined by pilot application protocol.

7.Risks

The personal risk by participating in this study does not exceed the risks of daily and normal life. None of the procedures pose danger to health or to physical and mental integrity.

The SMARTsurg project will ensure participants' safety throughout the research activities carried out. It is pointed out that the robots used for the purposes of the project experiments are friendly collaborative robots during the design of which special attention has been given to human safety. Additionally, in case of illness or accident during the survey, the responsible researcher who conducts the experiment is responsible for calling for immediate assistance that will provide you with first aid. If you are injured as a direct result of your participation in the pilot application, you will receive appropriate medicval care without needing to spend your own expenses. The provision of medical care does not mean that the pilot partner is responsible for the injury.

8.Compensation

Participants may be compensated for their participation. Employees who participate as part of their normal work hours will receive no other compensation. Other volunteers may be compensated their time, but special attention will be paid to avoid any form of unfair inducement.

9.Consent

I have read and discussed the content of the present form with a representative of the pilot application personnel. I have understood the subject of the research, I have had the opportunity to ask questions and all my questions were adequately answered. I studied each page of the present consent form, a copy of which was given to me. I had sufficient time for making my decision regarding my participation to the pilot application, to which I will attend voluntarily.

By signing the present form, I understand and consent freely that my personal data, my name and contact details, will be processed by [*define partner*], according to the procedure defined in section 2, in accordance with applicable laws and with what is stated in the present clause.

I have been informed regarding the research Project SMARTsurg and its purposes. I understand that my personal data will be encoded in order to safeguard confidentiality and that if results of the study are published, my identity will not be revealed. I also understand that I have the right to request access to my personal data, to correct, if applicable, and delete my personal data in conformity with the applicable legislation. For these purposes, I can contact *[define person in charge]* at the address provided above (see section 3).

I understand that after the study has been completed, my personal data will be deleted and will therefore no longer be available for amendment.

I have read the above and I understand that I can refuse to participate in this study without any direct or indirect negative consequence on my life.

By signing the present form, I agree with the above stated.

Signature of participant	Place/Date
Name of participant	e-Mail
Address and Telephone Nr.	
Signature of Investigator (Person received the consent form)	Place/Date
Name of Investigator	e-Mail
Address and Telephone Nr.	

Annex III: Good Research Practice at University of the West of England

University of the West of England

BRISTOL

Good Research Practice at UWE

Checklist and Guidance Notes

(Version 1.0, August 2015)

Contents

The Research Governance Team

The Research Governance Team will take queries from research staff, research students, and student supervisors in relation to any aspect of research governance. If we don't know the answer, we will try to find out; and if we are not the right person, we will tell you who is.

The UWE Code of Good Research Conduct

The key document to read as a researcher is the new ***UWE Code of Good Research Conduct*** *("the Code")*. This document highlights all the key issues for the good governance of research, and provides links to sources of further information. The *Code* can be accessed at http://www1.uwe.ac.uk/research/researchgovernance.

What is research governance?

There is a lot of different terminology used around research conduct. Research integrity is what we are trying to achieve. Good research practice is what we do to achieve integrity in our research. Good research conduct is demonstrated when our research practice is of a sufficiently high standard to ensure that integrity is upheld. Research misconduct, as defined in the *Concordat to Support Research Integrity*, is behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. **Research governance is the framing within which we manage research to ensure research integrity is achieved**. This framing includes **principles, legal and regulatory provisions, standards of good practice, policies, guidance, systems, management and supervision**; and spans institutions and in some cases national boundaries.

The Concordat to Support Research Integrity

There has been an increasing amount of focus on integrity in research over the last few years. This has culminated, in the UK, in the *Concordat to Support Research Integrity* 2012.The core elements are set out as:

- **Honesty** in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.

- **Rigour**, in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.
- **Transparency and open communication** in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.
- **Care and respect** for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

The *UWE Code of Good Research Conduct* is set in the context of the Concordat, and sets out what is necessary so that the University will be compliant with it.

Who is responsible for the research

Every piece of research, internally or externally funded, has a UWE Project Manager. This is usually the PI, or for student research the supervisor or DOS, and for research undertaken as part of individual scholarship this is the individual concerned. This role is often not the same as the day to day project management of the project, but brings with it certain responsibilities. These are set out in the *UWE Code of Good Research Conduct* at **Section 4**. Whilst the Project Manager has overall responsibility for the project, all those involved are responsible for their own role. The University is also responsible at an organisational level for research conducted under its auspices, and a diagram illustrating the Governance Structure is at **Annex 4 of the *Code***.

So what should I be thinking about?

The draft checklist and associated guidance notes at **Annex A and B** of this document can be used as a prompt, to make sure you are addressing all of the governance areas relevant to your research project. Not all research will need to address all of the items on the checklist; it will very much depend on what you are doing.

It is not a mandatory requirement at UWE to fill in the checklist - it is simply intended to be something which helps you in the necessary task of evaluating the governance aspects of your research. If fully completed, the checklist will also provide a record that you have considered the governance of your research, and it can also be forwarded to others whose advice and support you may seek (e.g. the Governance Team, or Contracts & Legal Team colleagues).

Annex A – The UWE Research Governance Checklist

Guidance on using this checklist

1. The UWE Research Governance Checklist is a tool to help UWE researchers ensure that you have fully reviewed the Research Governance matters that may apply to your research project. The checklist does not need to be formally reviewed within UWE, but instead should be used as a tool for discussion and planning within the research team. It is not a mandatory requirement to fill in the checklist, or even an expectation, that you will use it. It is simply intended to be something which helps you in the necessary task of evaluating the governance aspects of your research, or your student's research. If fully completed, the checklist does provide a record that you considered the governance elements of the research, and it can also be forwarded to the governance team (or others whose advice and support you may seek, such as Contracts team colleagues) for advice: researchgovernance@uwe.ac.uk.
2. This checklist provides a prompt of various Research Governance matters that could apply to a UWE research project. However, this list is not exhaustive and so if you have any concerns around research governance issues that fall outside of this checklist then do not hesitate to contact the UWE Research Governance Team.
3. Given that this checklist serves to provide prompts around various research governance matters, not all sections will be relevant to your research project. Therefore select 'Not Applicable' if that section does not apply to your research and move onto the next question.
4. Where a question does apply to your research (if you are in doubt, then we recommend that you assume that it does), then you should carefully consider the Advisory Notes associated with that question. The Advisory Notes will give you further information about what you need to do next to ensure that your research complies with UWE, national or international research governance requirements in that area. [HAS Researchers, please note that the guidance contained here is the same as the guidance in the HAS Research Governance Record].
5. If you feel that appropriate arrangements are in place for this area of your research, then tick 'Yes' and move onto the next question. You may want to make a note of your reason for giving this answer, as this will provide the record that you have fully considered the governance elements of the research.
6. If you feel that appropriate arrangements are not yet in place, then select 'No' or 'not sure' and follow the advice given in the Advisory Note on the recommended next steps. Again, you may wish to make a note of your reason for giving this answer, and the steps that you have taken to address any outstanding issues.
7. If you have any concerns with regards to the research governance of your research project, then we recommend that you complete the checklist in the first instance. If you continue to have questions then send your completed checklist to researchgovernance@uwe.ac.uk with some indication in the covering email of your concerns and we will get back to you as soon as possible.

UWE Research Governance Checklist

Essential information about the project		
Project PASS Ref: (For internally funded research, FREC Ref and/or other internal ref where available)	**UWE Project Manager:** (See Advisory Note 1)	**Project Title:**
Student Name: (Where applicable, see Advisory Note 1)	**Level of Study:**	
Project Start Date:	**Project End Date:**	**UWE Project Funding:**
Application stage or approved proposal:	**Internal Collaborators:**	**External Collaborators:**
Project Funder:		

Item to be considered	**Yes/No/Not Sure/Not Applicable**	**Notes and issues** *Please use the space in each section below to record any points you wish to have a record of, or queries you need to address or seek advice on. The boxes will expand as necessary.*
Funder requirements, Roles and Responsibilities, Contracting and Insurances		
Have you considered and addressed the funder requirements for your research project? (Please consult Advisory Note 2).		Notes:
Are there external collaborators involved in the project (including students) and have you considered what contractual arrangements might be necessary? (Please consult Advisory Note 3).		Notes:

Will the project create or use Intellectual Property, have you discussed this with Tech Transfer (RBI), and have appropriate agreements been set in place via the Contracts & Legal Team? **Note:** If confidential information is to be exchanged at the bid stage, a Non-Disclosure Agreement should be put in place prior to bid development. (Please consult Advisory Note 4).		Notes:
Will any UWE staff need an honorary contract, Research Passport or similar to allow access to the resources of a collaborating organisation? (Please consult Advisory Note 5).		Notes:

Item to be considered	**Yes/No/Not Sure/Not Applicable**	**Notes and issues** *Please use the space in each section below to record any points you wish to have a record of, or queries you need to address or seek advice on. The boxes will expand as necessary.*
If there are, or will be, any individuals holding honorary positions or who are appointed to joint employment roles involved in the project, is there clarity (supported by appropriate formal paperwork) on which responsibilities and liabilities lie with which employing organisation? (Please consult Advisory Note 6).		Notes:
Will volunteers or public research partners play a role in the research? If so, have data protection / other obligations been made clear in a legally binding agreement between UWE and the volunteer? (Please consult Advisory Note 7).		Notes:

Will the research be covered by UWE's standard insurance policies? If not, have you consulted with the UWE Insurance Officer to request adequate cover? (Please consult Advisory Note 8).		Notes:
Project Health and Safety Risk Assessment		
Are all 'suitable and sufficient' risk assessments in place for the project? (Please consult Advisory Note 9).		Notes:
UWE Ethical review (all projects with human participants, their tissue or data)		
Will UWE FREC or UREC review be needed? (Please consult Advisory Note 10).		Notes:
Working with vulnerable groups		
Does the project involve working with children or vulnerable adults (or their data)? (Please consult Advisory Note 11).		Notes:
Does the project involve taking, storing or using images of children or vulnerable adults? (Please consult Advisory Note 11).		Notes:
Does the project involve offenders, HMP Services or Probation Services? (Please consult Advisory Note 12).		Notes:

Item to be considered	Yes/No/Not Sure/Not Applicable	Notes and issues *Please use the space in each section below to record any points you wish to have a record of, or queries you need to address or seek advice on. The boxes will expand as necessary.*
Does the project involve adults who potentially lack or may come to lack mental capacity? (Please consult Advisory Note 13).		Notes:
Does your research involve issues which might be relevant to radicalisation? (Please consult Advisory Note 14). If you do not feel comfortable answering this question, please contact the Research Governance Manager for advice.		
Health related research, including department of health approvals		
Is UWE the project sponsor as defined under the DH Research Governance Framework? (Please consult Advisory Note 15).		Notes:
Will the project require HRA, NHS or Social Care Research Ethics Committee Approval and/or R&D management approval? (Please consult Advisory Note 16).		Notes:
Does the project involve human tissue? (Please consult Advisory Note 17).		Notes:
Does the project involve a clinical trial (not of a medicinal product or device)? (Please consult Advisory Note 18).		Notes:

Does this project involve a clinical trial of an investigational medicinal product (CTIMP)? (Please consult Advisory Note 19).		Notes:
Does this project involve a trial of a medical device? (Please consult Advisory Note 20).		Notes:
Research Data Management		
Does your project include collecting and 'processing' of personal data? If so, then are appropriate arrangements in place to ensure compliance with the Data Protection Act 1998? (Please consult Advisory Note 21).		Notes:
Are there appropriate arrangements in place for research data management? Does the project have a Data Management Plan? (Please consult Advisory Note 22).		Notes:
Item to be considered	**Yes/No/Not Sure/Not Applicable**	**Notes and issues** *Please use the space in each section below to record any points you wish to have a record of, or queries you need to address or seek advice on. The boxes will expand as necessary.*
Are adequate data security arrangements in place? (Please consult Advisory Note 23).		
Does your research involve security sensitive material? (Please consult Advisory Note 24). If you do not feel comfortable answering this question, please contact the Research Governance Manager for advice.		
Other Research Governance issues		

Does the project involve a significant international element? If so, have adequate measures been taken to ensure ethical review, consenting, contracting, legislation in other countries, data security, import/export of human tissue, foreign office advice, risk assessment as described in Advisory Note Section 9, insurance? (Please consult Advisory Note 25).		Notes:
Does the project involve Genetically Modified Organisms (GMOs)? (Please consult Advisory Note 26).		Notes:
Does the project involve working with animals (vertebrates or invertebrates) or animal byproducts? (Please consult Advisory Note 27).		
Does the project involve radiation? (Please consult Advisory Note 28).		Notes:
Have you considered any Export Control or dual use implications of your project? (Please consult Advisory Note 29).		Notes:

Intellectual Property

- Almost all research activity will involve some form of intellectual property. The University requires all research where intellectual property is involved to be subject to adequate legal arrangements before the commencement of any research. Where the research involves any party outside of the University (such as another research institution or industry partner) then an appropriate legal agreement must be entered into and agreements must be set in place via the Contracts & Legal team, who will work in collaboration with the Technology Transfer Manager (contact the appropriate Contracts Manager for your department or service).
- If you expect commercially exploitable intellectual property to arise from your project, you should contact the Technology Transfer Manager directly to discuss how this might best be managed (tech.transfer@uwe.ac.uk).
- **Note:** As UWE students are usually considered to be an external party, they would own their own results and IPR in the research. **If a funding body or collaborator owns the IPR of the research, and students are working on the project and producing results, then an IP agreement will be needed with the student otherwise the University will be in breach of the funding terms or collaboration agreement!** Therefore it is essential to ensure that appropriate agreements are in place between the University and students involved in research to secure Intellectual Property Rights.
- Further information can be found in Section 15 of the *UWE Code of Good Research Conduct* and from the UWE Intellectual Property Policy and Regulations at: http://www1.uwe.ac.uk/aboutus/policies.
- Advice on the protection and exploitation of IP can be obtained from the Technology Transfer Manager (tech.transfer@uwe.ac.uk).

Volunteers and Public Research Partners

- Research conducted in collaboration with statutory organisations (such as the NHS) are increasingly requiring that service users or carers are included within the research project team to ensure that the views and needs of these important groups are considered during the course of the research.
- Whether public research partners are volunteers, have their expenses reimbursed, or are paid for their time, they should be considered to be conducting business on behalf of the university and therefore be deemed to fall under UWE's liability and insurance policy cover.
- In order to be covered by UWE insurances, public research partners must be appropriately skilled, trained and supported in their work on the project.
- Public Research Partners must also sign a legally binding Letter of Agreement between themselves and UWE, which will clearly define their role and confirm that they have read and understood key UWE policies and guidance, for example on Data Protection, Risk Assessment, and Safeguarding.
- For further information on Letters of Agreement for Public Research Partners contact the Research Governance Team (researchgovernance@uwe.ac.uk, or ext. 81644).

Insurance

- The University is indemnified by its insurers, up to certain limits, for an employee undertaking research work, provided the employee acts within the scope of her/his employment, on approved research work undertaken for the University.
- For students, cover applies for a student working within the terms and conditions of the programme of study, under appropriate supervision, and where the student complies with Supervisor instructions.
- The University's insurance policies exclude cover for research involving nuclear waste, nuclear fuel, and hazardous properties of any explosive nuclear assembly or nuclear component. Therefore if your research will involve any of these you must contact the UWE Insurance Officer to organise appropriate extension of cover (john2.elliot@uwe.ac.uk).
- The University's policy also excludes clinical trials involving:
    - Investigating or participating in methods of contraception ○ Assisting with or altering the process of conception ○ The use of drugs or nutrients ○ Surgery (other than biopsy) ○ Genetic engineering ○ Subjects under 5 years of age ○ Subjects known to be pregnant
    - Pharmaceutical products / appliances designed or manufactured by the institution.
- Therefore if your research will involve any of these you must contact the UWE Insurance Officer to organise appropriate extension of cover (john2.elliot@uwe.ac.uk).
- Further information can be found in Section 16 of the *UWE Code of Good research Conduct* *http://www1.uwe.ac.uk/research/researchgovernance.aspx*.

Health & Safety Risk Assessment

- All research projects should be subject to an appropriate, suitable and sufficient risk assessment before research commences, i.e. it should identify the hazards (work activities and/or workplace), who might be harmed, the level of risk and any measures to control/manage the risk. This assessment need not focus on a risk that is every day or is trivial by virtue of it being either very unlikely to happen or the consequence would probably be very minor e.g. an aircraft crashing onto a Campus, or cuts from edges of paper.

- Risk Assessment is a University requirement, and ensures the safety of researchers, research participants and others affected by the research. The risk assessment is vital in ensuring that you have appropriately considered the potential risks associated with your research and is also evidence should something go wrong.

- If you are conducting research where a risk assessment is necessary and you fail to do one, this is in breach of the University's policies, and could be considered to be 'wilful negligence", which could mean that you are not covered by UWE's insurance, and therefore personally liable.

- In some circumstances it may be necessary for more than one risk assessment to be completed, particularly if there are different activities taking place during your research (e.g. where different chemicals or procedures will be used in the lab, or if research is to take place with different participant groups in different locations, or involving different researchers).

- Risk assessment should not be treated as a form filling exercise, and the UWE Project Manager must ensure that the appropriate control measures identified during the risk assessment process are put in place before the research commences (e.g. there may be specific training that the researcher requires). It should also be reviewed and ongoing throughout the research.

- Researchers should note that hazards may be psychological as well as physical, especially if the research involves conducting interviews or similar with research participants. The well-being of participants and researchers, and risks and mitigations for emotional distress should be included in the risk assessment, as appropriate.

- Once the risk assessment form has been completed and endorsed, please keep it on your central project file as it may be requested at any time by UWE, your funders, research participants, project collaborators or others e.g. insurers, the Health and Safety

  Executive (HSE) etc. This will also be evidence that you have acted in accordance with UWE's and legislative requirements in the event of any health and safety incident occurring.

- You should review your risk assessment at appropriate points in your research to ensure that the control measures identified are being implemented, and importantly whether the risk and control measures need to be amended in the light of the project progress. You must record on your project file when you have reviewed your project risk assessment and changes or action arising.

- Please note that for HAS faculty projects, your risk assessment must be submitted along with your application for UWE Ethical Review.
- Further information can be found in Annex 6 of the *UWE Code of Good research Conduct* and further guidance can be obtained from the UWE Health and Safety Standard HSS14 'Risk Assessment' at: http://imp.uwe.ac.uk/imp_public/displayentry.asp?URN=8043&return=false.

UWE Ethical review

- UWE requires that all projects that involve human participants, their tissue or their data undergo UWE ethical review, as detailed in the UWE Research Ethics Policy and Procedures: www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx
- Researchers conducting research which does not involve human participants but which is high risk or has potential for negative impacts on the environment or society should consider submitting an application for ethical review: where the research is involved with endangered, vulnerable or threatened species or populations; introduces material into an environment of a species or type not previously present; constitutes significant intrusion or destruction into an environment; disturbance to an ecosystem; causes deliberate damage or harm; pollution; removes plants or animals from an environment; is culturally or socially controversial or potentially infringes the rights of others.
- Research which has potential for 'dual use' (where the tangible and intangible features of a technology enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications) where significant harm could occur should also be submitted for ethical review. Further information on Dual Use is also given in section 29 below.
- Projects should normally be submitted to the UWE Faculty Research Ethics Committee (FREC) in the home faculty of the UWE Project Manager for that research project, except where projects involve surveying on a university-wide basis. In this case the project should be submitted to UREC for ethical review.
- Research projects that originate from a UWE Project Manager based within the Professional Services should also be submitted to UREC for ethical review.
- If your project has already undergone ethical review by an appropriately constituted external research ethics committee (REC) and received a favourable opinion then a streamlined process of ratification by UWE FREC/UREC will be followed. This ensures that issues local to UWE are considered, and ensures that UWE retains the final 'sign off' on the project.
- Examples of appropriately constituted external RECs include an NHS or Social Care REC, another university REC, or the National Offender Management Service ethical review process.
- In order to ratify an external ethical opinion, the UWE Project Manager must submit the application form which was submitted to the external REC, along with any accompanying documentation (e.g. protocol, patient information sheets, questionnaires and consent forms), and the favourable opinion letter.
- These will need to be submitted to the Faculty Research Ethics Committee (FREC) for ratification before you begin any work with research participants, their tissue or their data.
- Whilst Service Evaluations within the NHS (as per the Health Research Authority definitions) do not require NRES ethical review, UWE ethical review of these projects is required. This demonstrates the highest standards of integrity, and increasingly,

reputable publishers will not publish without some evidence of ethical review. Other evaluation research must be submitted for University ethical approval. See www1.uwe.ac.uk/research/researchethics/guidance.aspx for further guidance on the ethical review of evaluation research.

- You must not commence your research on the part of the project that requires Research Ethics Review until approval has been obtained.

Working with children and vulnerable adults, or their data

a) Safeguarding Training

- All UWE researchers undertaking research with children or their data are required to have safeguarding training and be familiar with UWE policy and procedures relating to Safeguarding. Further details can be found on the research Ethics Guidance webpage: www1.uwe.ac.uk/research/researchethics/guidance.aspx
- UWE is currently developing in-house safeguarding training for researchers, but this is not as yet available. However, there are off-the-shelf modules available on-line:

  http://www.nspcc.org.uk/Inform/trainingandconsultancy/onlinetraining/online-childhttp://www.nspcc.org.uk/Inform/trainingandconsultancy/onlinetraining/online-child-protection-introduction_wda102265.htmlprotection-introduction_wda102265.html
  (Costs £20).

b) Gaining Consent

- **The consent of the parents or legal guardian would normally be sought in advance of approaching a child under 16 years old.** The child themselves would then be approached for consent. In certain circumstances (for example in clinical trials), where research involves a baby or a very young child, consent from their legal advocate (parent/guardian) may be sufficient on its own and is required where capacity to consent is clearly shown to have been explored and not found to be possible. In all other circumstances it is essential to gain the consent of a child participant.
- Consent should be documented in an auditable record (e.g., a written record or audiorecorded verbal consent). Researchers should ensure that parents/guardians are informed about the nature of the study and given the opportunity to withdraw their child from the study and, ideally, positively affirm their participation (actively 'opt in'), providing it does not conflict with the child or young person's interests. The child's consent will always be necessary. Best practice would usually be not to go ahead with the study unless both the child and parent agreed to participation.
- Researchers should pay particular attention, especially with younger children, to ensuring that there is 'continuous consent' throughout the interview or other research process. This may involve being attuned to non-verbal cues, and researchers should stop the research process if there is any doubt about whether the child wishes to continue.
- Where the child satisfies the criteria for what the law refers to as "Gillick competence" and where it is not appropriate to seek parental consent, for example where children may have parents who are unlikely, unable or unwilling to send back a written consent, or where the child, for good reason, may be reluctant to have their parents know of their involvement (an issue which, for example, may typically arise in relation to sexual health research), then research **can proceed** with the consent of the child, but without the consent of the parent. However, researchers should always carefully

consider whether good research practice suggests that parental consent should also be obtained.

c) Disclosure and Barring Service Checks

- Current DBS checks will be needed for all staff working directly with children on the research project. Any other researchers (including students) working directly with children on the project must also have current DBS checks.
- It is your responsibility to safely hold a copy of your DBS check, which should always be easily available for inspection should the need arise.
- Where it is deemed necessary for DBS checks to be completed, the UWE Project Manager should obtain evidence from the appropriate nominated person that all UWE staff, students and volunteers working on the project have current DBS certificates, and record the reference number and the date that the certificate was issued.
- DBS checks should be renewed every 3 years. Further details can be found in the UWE Disclosure and Barring Service Policy:
  (www1.uwe.ac.uk/aboutus/departmentsandservices/professionalservices/humanresourc es/hrpoliciesandprocedures.aspx).

d) Images of children or vulnerable adults

Special care should be taken in relation to taking and using images of children or vulnerable adults. If you have queries in this regard, contact the Research Governance Team for guidance (researchgovernance@uwe.ac.uk).

Mental Capacity Act (2005)

- The Mental Capacity Act (MCA) is designed to protect and empower individuals who may lack the mental capacity to make their own decisions about their care and treatment. Further details can be found at: www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf. The central principle of the Act is that people should not be excluded, but facilitated to be included, so it is not a simple matter of excluding people who may not have capacity.
- If you are (or may be) working with adults who potentially lack or may come to lack capacity, you must fully understand the provisions of the Mental Capacity Act (2005), as consideration must be given to individuals who may, or may not, be able to consent to their involvement in your research. Appropriate provisions must be made for individuals who are unable to consent to their own involvement in research.
- Practical guidance on how the Act operates on a day-to-day basis, and examples of best practice for carers and practitioners are given in the Code of Practice: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224660/Mental_Capacity_Act_code_of_practice.pdf
- Your research may involve individuals that lack capacity, even if it is not your deliberate intention to target them. Individuals can move in and out of a state of capacity over time, it is not always a permanent feature of that individual. Mental health and drug and alcohol issues can affect the capacity to consent to research.
- Under the Mental Capacity Act 2005, ‘intrusive’ research requires approval from an NHS or Social Care REC if it will at any stage involve people unable to consent for themselves because of an impairing condition. Intrusive procedures are those requiring consent in law, including use of identifiable tissue samples or personal information.

Radicalisation and vulnerable individuals

- UWE needs to be aware of any research that may potentially have an influence on radicalisation, and ensure that it is appropriately reviewed. The University will need to assure itself through the ethical review process that the research is appropriate per se, and appropriate for the level and experience of the researcher.
- In relation to student research, there is also a need to have an awareness of the potential for the student's participation in the research (or even the refusal to allow them to conduct a proposed piece of research) to contribute to their radicalisation, or for the choice of research project to flag that radicalisation is a risk.
- UWE is currently developing processes and procedures to manage these requirements, but in the meantime, if you feel that your research may have the potential to contribute to

  the radicalisation of vulnerable individuals, then please contact the Research Governance Manager to discuss further.

Is UWE the project Sponsor under the DH Research Governance Framework?

- The Research Governance Framework for Health and Social Care outlines principles of good governance that apply to all research within the remit of the Secretary of State for Health (see: www.gov.uk/government/publications/research-governance-framework-forhttp://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-editionhealth-and-social-care-second-edition). In practice this means any research undertaken in or through the NHS or social services, which involves human participants or their organs, tissue or data.
- All research that falls within the Research Governance Framework must have a Sponsor. This is the organisation responsible for securing the arrangements to initiate, manage and finance a study. The Sponsor will usually be one of the organisations taking the lead for particular aspects of the arrangements for the study, for example the employer of the Chief Investigator, the main funder or the lead health or social care provider.
- A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make appropriate arrangements to allocate and where appropriate to delegate all the responsibilities within the Research Governance Framework that are relevant to the study.
- Given the responsibilities and liabilities associated with the Sponsors' role, UWE would usually only agree to act as Sponsor (or as joint or co-Sponsor) for projects where the Chief Investigator (CI) is a UWE member of staff, or a UWE postgraduate research student for whom the Director of Studies is a UWE member of staff.
- However, being the employer of the CI does not automatically mean that UWE should take on the Sponsors' role. It may be more appropriate for the main funder or lead collaborating health or social care organisation to take on this role.
- You must have approval from the Associate Dean responsible for research within your faculty before UWE can take on the Sponsors' role. This will usually be managed when

  an application for NHS or Social Care REC approval for the project is made through the IRAS system (see section 16 below), as the UWE REC Chair will review your application in advance of submission, and make a recommendation to the Associate Dean as to whether UWE should act as Sponsor for your project.
- As detailed in the previous section, all applications made through IRAS for REC or R&D approval must be scrutinised by the Chair of your Faculty Research Ethics Committee before they are submitted. The Chair will note where it is proposed that UWE is the sponsor of the project and will forward the application onto the Associate Dean responsible for research within the faculty, with a recommendation of whether it is appropriate for UWE to act as Sponsor in this case or not. The Associate Dean must electronically authorise the IRAS form to confirm that UWE is willing to act as Sponsor for this study, and it will not be possible to finally submit the form until this is done.

- If you have any questions about the Sponsor role for your study, please contact the Chair of your Faculty Research Ethics Committee or the Research Governance Team for further guidance.

HRA, NHS or Social Care Research Ethics Committee Approval and /or R&D

Management Approval

You must have Health Research Authority (HRA) approval (for some studies from May 2015), or a favourable ethical opinion from an NHS or Social Care Research Ethics Committee before you can begin your research if your research involves:

- NHS or Social Care staff
- Patients that are under the care of the NHS or social services
- Organs, tissue or data of NHS or social services patients
- Carers of NHS or social services patients

The procedure that you need to follow will depend on whether UWE is the Sponsor of the research under the Department for Health Research Governance Framework. Further information on Sponsorship can be found in Section 15 above.

a) If UWE is the Sponsor of the research

You must have approval from the Associate Dean responsible for research within your faculty before UWE can take on the Sponsors' role. See section 15 above for further details.

- You will need to apply for HRA approval or NHS or Social Care Research Ethics Committee (REC) review using the Integrated Research Application System (IRAS): https://www.myresearchproject.org.uk/.

****NEW May 2015****

- The Health Research Authority (HRA) is implementing changes in the way in which governance approvals are given for NHS studies in England. There is a phased implementation of these changes, and so the type of research that you are conducting will determine whether you need to apply for new HRA Approvals or old style NHS REC Review and accompanying R&D Management Approvals.
- The new HRA approval procedure will incorporate both the NHS REC review, and local R&D reviews. When HRA Approval is fully rolled out, it will remove the need for NHS permission to be issued by each participating organisation and will replace the local R&D approval process.
- In line with the phased implementation, the following study types are eligible apply for the new HRA approval from the dates given below:
  - Studies involving NHS staff that do not require NHS REC approval – from 11th May 2015
  - Studies taking place in primary care independent contractor settings (NHS GP practices, dental practices and community pharmacies) – from 10th August 2015
- Guidance on applying using the new HRA approval procedures can be found at: www.hra.nhs.uk/resources/hra-approval-applicant-guidance/.

- At the present time, all other studies will need to follow the usual NHS REC and R&D approval processes (see: www.hra.nhs.uk/research-community/applying-forhttp://www.hra.nhs.uk/research-community/applying-for-approvals/approvals/).
- If you will need NHS R&D approval, you can also apply at the same time as you apply for REC review using the appropriate forms on IRAS. This ensures that your applications are integrated and occur simultaneously.

In all cases, your IRAS Forms must be reviewed by the Chair of your UWE Faculty Research Ethics Committee (FREC) prior to submission. IRAS Forms should not be submitted without prior review by the Chair.

- If approved by the Chair of the UWE REC, and by the Associate Dean as the Sponsors Representative, then the form will be electronically authorised and submitted.
- If you receive HRA Approval or a favourable ethical opinion for your research then you must send a copy of your final IRAS application forms, the HRA or REC decision letter, and any other supporting documentation to researchethics@uwe.ac.uk for review and 'ratification' by the Chair (or nominee) in the context of UWE-specific concerns. This approach has been designed to retain the right of ultimate 'sign off' by the University, and to ensure that local issues are addressed.

You should not proceed with your research project until you have UWE ethical approval for your research.

- You must always retain all information in relation to ethical applications and approvals on your project file.
- If you are working in the NHS or Social Care, even if you do not need ethical approval from an NHS or Social Care REC, you may need the new HRA or old-style R&D approval from the NHS, and this can still be applied for using IRAS.
- If you are conducting service evaluation research (in any setting), and NHS or Social Care REC approval is not required, you will still need approval from a UWE Research Ethics Committee, and you may need the new HRA Approvals or old-style R&D approval from the NHS or Social Care organisations that you are working with.
- If you plan to make any changes to your research after a favourable ethical opinion has been granted you must inform the HRA / NHS / Social Care and UWE Research Ethics Committees of your proposed changes
- If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee. Further guidance on amendments is available at: www.hra.nhs.uk/research-community/during-yourhttp://www.hra.nhs.uk/research-community/during-your-research-project/amendments/research-project/amendments/

b) If UWE is not the Sponsor of the research

If UWE is not the sponsor of the research, you will need evidence from the Sponsor of HRA approval, or NHS or Social Care Research Ethics Committee favourable opinion.

This will need to be submitted along with your application for UWE FREC / UREC ratification before you can begin your involvement in the research.

Data Protection

Data protection and data security is the responsibility of every member of UWE staff who processes personal information. All staff must read and comply with the following UWE guidance: http://www.uwe.ac.uk/finance/sec/dp/index.shtml

The following key points are taken from the Jisc Legal Guidance: *Data Protection and Research Data: Questions and Answers*, and further information can be found by following the hyperlink.

- If personal data is collected during the course of research then that data will be subject to the Data Protection Act 1998.
- 'Personal data' means information that relates to an identifiable living individual, as well as information which, when combined with other data accessible to the researchers, would permit the individual's identification.
- 'Sensitive personal data' is subject to more stringent rules and requires more careful consideration.
- Data that has been anonymised and so cannot be linked to an identifiable living individual is not personal data and thus in principle falls outside of the Data Protection regime.
- Data is only truly anonymised when an individual can no longer be identified from it. A dataset that has been 'link-coded', with names and other key identifiers removed, but which is linked to a separate file held by, or accessible to, the researcher which enables individual research subjects to be identified (e.g. consent forms) is not anonymised, but pseudonymised.
- For pseudonymised data, both raw datasets containing names and other key identifiers, and pseudonymised datasets capable of linkage to identifying data will be subject to the DPA 1998.
- A key principle of data protection is 'data minimisation', i.e. if data is not collected, the risk of its future misuse is automatically reduced. In the research context consider whether satisfactory research outcomes can be achieved without collection of personal data or with only minimal collection of personal data.

At the point of data collection a Data Protection Privacy Notice **must** be included on all forms / surveys / questionnaires / on-line training etc. when collecting personal information from any medium, **including via the internet/intranet**. This should include information such as who you are, the name of the institution that will hold the data, what you are going to do with their information, who it will be shared with, how it will be stored and what will happen to the data once the research is concluded. Further advice can also be sought from the UWE Data Protection Officer (john2.elliot@uwe.ac.uk).

Data Management Plan

- Research data is all data arising as a result of a research project. This includes raw data, analysed data, and also data which arise during the course of research which is later translated into another form or destroyed, such as audio and video recordings.
- Research data management refers to all aspects of data management concerned with research, from developing a data management plan at the inception, through the life cycle of the project, to the archiving and making available, where appropriate, of

  research data. Inadequate attention to research data management can result in serious research misconduct, including breaches of confidentiality, or errors in reported data.
- UWE recommends that a Research Data Management Plan is developed for every research project. Further information can be found at: www.uwe.ac.uk/finance/sec/dp/intranet/docs/F29.pdf and:

  http://www.uwe.ac.uk/library/resources/general/JISC_MRD/dataManagementPlan.pdf.
- In compiling your research data management plan, you need to make sure you think about data at every stage of your research, including data capture, transportation, immediate storage, storage during analysis, deletion in line with consent, long term storage, and possible archiving, as well as who can access the data at each stage, and, crucially, how data security, and how the data is to be backed up.

Data Security and Records Management

- You must make adequate arrangements for the security of your research data throughout its life cycle.
- It should always be clear who should have access to research data, and how.
- Data should be securely stored and backed up. Research data should only be held on University storage devices, never on personal PCs, for example.
- Special care should be taken in the transportation of research data. This includes not emailing data (as this is not secure); ensuring that all data in transit is encrypted; ensuring that data is not left unattended during transit (for example video tapes or questionnaires being transported from a research site to the University).
- Where data is not to be held on UWE premises, careful thought will be needed to assure the security of the data at all times.
- In addition to the security of the research data itself, research records, including relevant permissions and reports, must be securely held on the Project file.
- Further guidance on data security will be issued in due course, but in the interim please consult the Research Governance Team researchgovernance@uwe.ac.uk if guidance is needed.

Security Sensitive Information

Security sensitive research can be of various kinds, e.g. research into military equipment, extremism by animal rights campaigners, or IT encryption design for public bodies. However, the focus of this guidance is research that utilises information related to terrorism.

UWE is considering its arrangements in relation to security sensitive information in response to the UK Government *Prevent* Duty Guidance: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417943/Preve nt_Duty_Guidance_England_Wales.pdf and the Universities UK guidance on use of security sensitive information in research:

www.southampton.ac.uk/corporateservices/rgo/media/OversightOfSecuritySensitiveResearc hMaterial.pdf.

UWE will be setting in place appropriate arrangements to address issues highlighted in the

UUK document. In the meantime, please contact the Research Governance Team for a confidential discussion if you feel that your research may fall within the scope of counterterrorism legislation.

Projects with significant international element

Much of the advice given previously relates to projects based predominantly in the UK. Research projects with a significant international element may require different research governance arrangements to be in place:

a) Contracting with International Partners

Collaboration agreements between overseas funders or partner institutions may need special consideration to ensure that due consideration is given to international legal requirements, or laws within the home country of overseas funders or partner intuitions.

Contracts and agreements with international partners for externally funded projects will be managed through the PASS process. However, if your project is internally funded and you know that you will need collaboration agreements with overseas partner institutions, or you have queries outside of this process, then contact the Contracts and Legal team via the appropriate Contracts Manager for your department or service.

b) Ethical and Health and Safety Considerations for Overseas Research Collaborators:

UWE researchers have a duty to be mindful of the health and safety of any researchers from collaborating organisations participating in UWE projects, even though they are not UWE employees or students. We should be mindful if, by involvement in a UWE research project, we are asking overseas collaborators to take risks greater than they would in the course of their normal activities.

Staff from organisations in the developing world may not have access to the level of H&S advice or equipment that we have here in the UK and this should be a consideration when planning the research, writing risk assessments, or budgeting for research resources for overseas collaborators.

If you need any further advice on this matter, then contact the chair of your Faculty Research Ethics Committee.

c) Ethical and Health and Safety Considerations for Overseas Research Participants:

Where the research involves research participants, their tissue or their data from overseas (and especially developing countries) then special consideration must be given to ensure that issues such as consent has been taken in line with local requirements (e.g. In India and Africa). This would normally be covered in your University Research Ethics

Application Form. If you need any further advice on this matter, then contact the chair of your Faculty Research Ethics Committee.

d) Import / export of materials

Human Tissue

The import of relevant material is not a licensable activity under The Human Tissue Act 2004 (HT Act), although the storage and use of that tissue once imported into the UK is covered by the HT Act. All bodies, body parts or tissue should be treated with respect and dignity. Researchers should read the Human Tissue Authority Code of Practice for Import and Export: http://www.hta.gov.uk/_db/_documents/Code_of_practice_8_http://www.hta.gov.uk/_db/_documents/Code_of_practice_8_-_Import_and_export_of_human_bodies,_body_parts_and_tissue.pdf_Import_and_export_of_human_bodies,_body_parts_and_tissue.pdf.

The consent provisions of the HT Act do not apply to imported material. UWE regards high standards in ethical consenting to be paramount in all research. The University will therefore only accept human tissue for research purposes (whether cellular or acellular) that has been ethically sourced. Ethical consenting must take place within the context of the particular Country concerned, and the procedures will therefore vary. Whilst cultural sensitivities must be respected, this should not lead to anything less than excellent ethical standards being in place. This is particularly the case in relation to vulnerable groups, which in different contexts may include women, children, older or poor people, people from certain ethnicities or other social categories or those who are in a negative power relationship with researchers or gatekeepers. It is the UWE Project Manager's responsibility to ensure that samples are ethically sourced and consented and if there is any doubt, those samples should not be collected or imported as part of the project. Such ethical judgements can be complex, and guidance is available from the HTSC via the Officer emma.youde@uwe.ac.uk.

e) Travel overseas by UWE staff

UWE staff must ensure that they have appropriate approval (e.g. from their Head of Department) for any research visits overseas. Staff must also check that the UWE Travel insurance policy provides sufficient cover for the activities that they may be undertaking during the course of their research visit overseas, see: www.uwe.ac.uk/finance/purchasing/documents/Travel_Insurance_Update_01082011.pdf.

A risk assessment, as detailed in Section 9 must be completed for all activities that are to be undertaken by UWE staff during the course of their research visit overseas. Depending on the country to be visited, you may need to seek travel advice from the Foreign and Commonwealth Office before travel. Please note: UWE insurances would normally be invalidated if you were to travel to a country against the advice of the FCO.

f) Data Protection and Data Management across International Boundaries

Staff should not send personal information outside the European Economic Area (EEA) unless appropriate data security measures (e.g. Data Processing Agreements) are in place. The following link provides a list of countries in the EEA:

www.companieshouse.gov.uk/about/miscellaneous/listeeaCountries.shtml

Further guidance can be found in the UWE Staff Guidance on Data Protection: www.uwe.ac.uk/finance/sec/dp/.

Research with animals or animal by-products

a) Research with animals

- Research on 'protected animals' is strictly regulated by the Home Office under the Animals (Scientific Procedures) Act 1986: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986
- "A protected animal" for the purposes of this Act means any living vertebrate other than humans, and any living cephalopod. **Research with live (or the killing of) such animals is only permitted on these animals under licence**.
- Researchers using tissues from protected animals obtained from a third party must ensure that the material was obtained legally and ethically before transferring any materials to UWE. **They should notify the designated lead person for animal research** in the Department of Biological, Biomedical and Analytical Sciences of their research plans.

To obtain the contact details of the designated lead on animal research please contact the Research Governance Officer or Chair of FREC.

- Examples of other research at UWE involving animals, which fall outside of the Animals (Scientific Procedures) Act 1986, are given below: ○ Work with nematode worms
  ○ Field work where animals may be disturbed ○ Ecological work including trapping and counting insects ○ Collecting lower animals from water sources.

- In all cases, researchers conducting such research should ensure that they:
  - Consider the 3Rs and harm/benefit assessment as part of the design and conduct of fieldwork studies/research with animals that are 'not protected'. This assessment is an integral part of the Animals (Scientific Procedures) Act 1986 and while research in these areas would not regulated by this Act, the assessment is still relevant to field work research which may have the potential to compromise the welfare of the study or non-study species (see: https://www.nc3rs.org.uk/wildlife-research).
  - Comply with other forms of UK legislation that may apply to this area of research (e.g. the Wildlife and Countryside Act 1981, see: http://www.legislation.gov.uk/ukpga/1981/69/contents).
  - **Formally request permission from the designated lead for animal research** based in the Department of Biological, Biomedical and Analytical Sciences in the Faculty of Health and Applied Sciences before commencing their research.

- The designated lead for animal research is responsible for ensuring that any ethical issues have been appropriately addressed by the researchers and advise whether a

full ethics application to the relevant Faculty Research Ethics Committee should be submitted for review.

- The designated lead for animal research will keep an auditable record of all research involving animals and produce an annual report for the University Research Ethics Committee detailing such research activity across the University.

b) Research with animal by-products

- The University must comply with the guidance and regulations from Department for Environment, Food and Rural Affairs in relation to animal by-products (ABPs), and must therefore register with DEFRA for the use of animal by-products in research. See: https://www.gov.uk/government/collections/guidance-for-the-animal-by-product-industry.

- Animal by-products include any part of an animal, regardless of where sourced. This includes, but is not confined to, feathers, uncured leather/fur, bone, honey, milk, skin, eggs, eyeballs, meat, aquatic and terrestrial invertebrates, serum/serum products.

- Your research **must be registered on the UWE Animal By-Products Research Register before you can bring samples onto UWE premises**. UWE is currently in the process of compiling its Animal By-Products Register, so please contact the Research Governance Team to ensure that your research is covered by the activities listed on the Register.

- In addition to inclusion on the Register, researchers must ensure that their research complies with the regulations set out in the DEFRA guidance (https://www.gov.uk/government/collections/guidance-for-the-animal-by-producthttps://www.gov.uk/government/collections/guidance-for-the-animal-by-product-industryindustry). Proper attention must be paid to handling and record keeping, from the time of acquisition to disposal. Samples must be properly labelled (including as being not for human consumption), and stored in leak proof containers. The method of destruction must be appropriate to the material, and records must be maintained for a minimum of two years.

Export Controls and Dual Use

Dual use is a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications.

Dual use technology is subject to a range of national and transnational export controls to prevent items with military or security applications from being acquired by those that might misuse them. Researchers should ensure that they are compliant with the relevant legislation and regulation, and ensure that they apply for the appropriate licences, if they are required.

Export controls apply to controlled items such as military equipment and 'dual-use goods' and to the 'technology' related to them. Export controls apply for 2 key reasons:

- Goods are specifically listed on the UK Strategic Export Control Lists.
- 'Catch-all' or 'end-use controls' which apply to goods that are not specifically listed on the control lists but are intended for weapons of mass destruction (WMD) related purposes.

Examples of the types of research that may be subject to dual use and export control legislation includes: nuclear physics; biological sciences (viruses, pathogens, synthetic biology); chemicals (toxic); high strength materials; high specification electronics; lasers and optics.

Research activities that may bring you within the scope of dual use and export control legislation includes:

- physical exports of 'technology' (e.g. laboratory equipment or samples, even small quantities)
- research agreements with overseas partners (which may involve the transfer or controlled technology or software)
- International travel (e.g. data or presentations on lap-tops, meetings with non-UK nationals)
- Teaching or supervising the research of international students.

You can read general information on controlled technology transfers in the guide on the export of technology.

Any members of the academic community who are impacted by export controls are strongly recommended to read the guidance and understand their responsibilities for obtaining a licence if required: https://www.gov.uk/export-control-legislation-for-uk-academics-and-researchers.

https://www.gov.uk/government/publications/guidance-on-export-control-legislation-forhttps://www.gov.uk/government/publications/guidance-on-export-control-legislation-for-academics-and-researchers-in-the-ukacademics-and-researchers-in-the-uk.

The EU perspective is given at: http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls/ http://trade.ec.europa.eu/doclib/press/index.cfm?id=1166.

In some instances, controls from other territories may apply in additions to UK-administered control. For example, **US Export controls are extraterritorial**, and attached to US products, software and technical data wherever they go, even after the incorporation into other articles.

Where 're-export' clauses apply, 'viewing' of US-controlled technical data by foreign nationals within the UK can be considered re-export, and so may not be permitted.

US-controlled items are common in the EU, especially within the aerospace, defence and dual use sectors, and their associated research. Further information about US Export Control legislation is given at: http://www.state.gov/strategictrade/overview/.

A breach of US Export Control laws would lead to significant penalties, including imprisonment for individual researchers, and the inclusion of UWE on the US "Denied Parties" list, which would have very severe consequences for the university. Further guidance can be obtained from the Research Governance Manager.

Annex C – Description of Research Misconduct

Research Misconduct includes (NB these detailed descriptions have not yet been approved by the University, but are included here for information):

Fabrication, including:

- deliberately making up research results/data, including documentation and participant consent, and presenting them as if they were real.

Falsification, including:

- manipulating research processes or changing or omitting data, imagery or consents without good cause, such that the research is not accurately represented in the research record;
- Fraud or other misuse of research funds or research equipment.

Plagiarism, including:

- the deliberate presentation of using other people's ideas, intellectual property or other material (written or otherwise) without giving proper credit or acknowledgement.

Misrepresentation, including:

- misrepresentation of data;
- deliberately, recklessly or negligently presenting a flawed interpretation of data; undisclosed duplication of publication,
- undisclosed duplicate submission of manuscripts for publication;
- misrepresentation of interests, including failure to declare material interests either of the researcher or of the funders of the research;
- misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held;
- misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution Deception in research proposals.
- Misquotation or misrepresentation of other authors

Failure to meet ethical, legal and professional obligations, **including**:

- failure to obtain, and comply with the terms of, appropriate permissions to conduct research, including ethical approval;
- failure to comply with legal and regulatory requirements;
- misuse of personal data;
- failure to follow accepted research procedures
- Failure to follow established protocols without good reason, and appropriate permissions, if this failure results in unreasonable risk or harm to research participants, animals or the environment

- attempting, planning or conspiring to be involved in research misconduct or inciting others to be involved in research misconduct

Mismanagement or inadequate preservation of data and/or primary materials, including failure to:

- keep clear and accurate records of the research procedures followed and results obtained including interim results;
- hold records securely in paper or electronic form;
- make relevant primary data and research evidence accessible to others for reasonable periods after the completion of the research: data should normally be preserved and accessible for 10 years, but for projects of clinical or major social, environmental or heritage importance, for 20 years or longer (N.B these periods are indicative, these have not yet been approved by the University);
- manage data according to the University's and the research funder's data policy and all relevant legislation;
- deposit data in line with the University's open access to research data policy;

Breach of duty of care, whether deliberately, recklessly or by gross negligence, including:

- breach of confidentiality, including disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality;
- placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated;
- not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently;
- not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment;
- improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes: failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes;
- facilitating of research misconduct by collusion in, or concealment of, such actions by others;
- intentional, unauthorised use, disclosure or removal of, or damage to, researchrelated property of another, including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.

Improper dealing with allegations of misconduct including:

- failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistle-blowers;
- failing to deal appropriately with malicious allegations which should be handled formally as breaches of good conduct;
- failing to report suspected research misconduct through the proper channels.

This list is not intended to be exhaustive. Honest errors and differences in, for example, research methodology and interpretations are not examples of research misconduct. Misconduct includes acts of omission as well as commission. The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgment that the misconduct was committed deliberately, knowingly, negligently or recklessly in the conduct of any aspect of a research project.