VECMA

D4.5: Ethics Report

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CONTRIBUTORS

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- Julien Abi Nahed
- David Wright
- Peter Coveney

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TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

No table of figures entries.

1   Executive summary

This deliverable describes the ethics framework within the VECMA project with the aim of ensuring that all datasets used and analyses conducted within the project conform to the EU and national legal and ethical requirements. The initial exemplar applications in the project have been designed to use open data and require no ethical approvals. An Ethics Advisory Board has been established to review any datasets or analyses to be added to the project, ensure that all the relevant ethical concerns are addressed and appropriate documentation is created and retained.

2   Composition and remit of the Ethics Advisory Board

The goal of the VECMA project is to create a software toolkit which facilitates and automates data analysis. Whilst the datasets used to test and develop the software are open and/or anonymised (details provided in Section 2.5) the Ethics Advisory Board (EAB) has been established to review all datasets and analyses which are incorporated into the project after its initiation. There is no intention for the VECMA project to become involved in any clinical trials.

2.1   Names and contact details of the Ethics Advisory Board

VECMA's Ethics Advisory Board is relatively streamlined as, where patient data is concerned, the project is primarily designed to use open and anonymised data in order to develop software tools. Should more complex issues arise, the panel is empowered to enlist support from experts in the relevant field.

EAB President and leader: Dr Julien Abi Nahed, JAbiNahed@hamad.qa , Hamad Medical Corporation, Qatar. Dr Abi Nahed is an academic research scientist who currently leads the Research & Development section at the Department of Surgery at Hamad Medical Corporation. He has extensive experience coordinating medically related research projects in different regulatory environments gained throughout his career, including at Ecole Centrale Paris in France, Siemens Corporate Research in the US and at the Qatar Robotic Surgery Center at Qatar Foundation.

Organisational relationship to the Coordinator:
1. Reviews all new datasets and analyses proposed for use in development and testing of VECMA tools (before submission to the different local ethical boards if appropriate),
2. Issues Ethical Report Forms to the Project Coordinator,
3. Gives final approval of the reviewed ethics proposals performed by other EAB members and submits to the Project Coordinator.

EAB member: Ms Kate Dunbar, kate.dunbar@brunel.ac.uk , Brunel University London, UK
Ms Dunbar is responsible for delivery of the research ethics activity at Brunel. She is also the secretary of the Brunel University Research Ethics Committee (UREC), which oversees all research ethics matters concerning research conducted by Brunel University staff and students which involves human participants, their tissue, and their data. This role provides her not only with a wide range of experience managing ethical issues in research but with contacts that will allow us to recruit experts to the panel to cover any issues which arise concerning EU or national privacy legislation.

Organisational relationship to the Coordinator:
1. Supports the EAB President in reviewing all new datasets and analyses proposed for use in development and testing of VECMA tools (before submission to the different local ethical boards if appropriate),

2. Recommends field experts to enhance the review process of projects where ethical concerns have been raised by the EAB.

EAB coordinator: Dr. Robin Richardson, robin.richardson@ucl.ac.uk , UCL, UK
Dr. Richardson is a postdoctoral researcher in cerebral blood flow simulations involved in a range of projects involving the analysis of potentially patient identifiable data.

Organisational relationship to the Coordinator:
1. Coordinates the EAB members' work and liaises with the Project Coordinator,
2. Monitors the storage of documentations associated to the Ethical review process, and the corresponding EAB and local ethical committee approvals.

2.2 Nature of Ethics Advisory Role

The role of the EAB is to review all datasets and analyses to be performed within the project. As such, the board will only be convened when new applications are to be initiated within the project as all initial datasets and analyses are free from ethical implications (see Section 2.5).
The review process will ensure that detailed information is kept on the procedures for data collection, storage, protection, retention, and destruction, and confirmation that they comply with national and EU legislation will be kept on file. Particular attention will be given to clinical or medically related datasets where information on the informed consent procedures with regards to the collection, storage, and protection of personal data will be kept on file. Templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) for all such projects will be submitted to the EAB, reviewed and kept on file by the EAB coordinator. For analyses which involve the further processing of previously collected personal data, relevant authorisations will be reviewed by the EAB and be kept on file subsequent to approval.

2.3 Duration of cooperation of the Ethics Advisory Board with the coordinator

The EAB composition was confirmed on the 23rd November 2018 and the board will continue to exercise its function until the end of the project (14th June 2021).

2.4 Requirements as set out in Ethics Screening and/or Ethics Assessment Report

The Ethics Screening for this project acknowledged that the general focus of the project is on simulation, but expressed concern with regard to the exemplar applications in the area of migration and biomedical research, as the consortium potentially will make use of personally identifiable data and therefore the status of these applications should be clarified. Moreover, relevant authorizations by local/national ethics committees shall be provided to REA & EC prior the execution of experiments. Moreover, it was asked to use publicly available data or fully anonymized data and not linked to an identity. As detailed in Section 2.5, the currently envisioned exemplar research will not make use of any personally identifiable data and requires no ethics approval.

2.5 Evidence of compliance with requirements of Ethics Screening and/or Ethics Assessment Report

VECMA project includes 6 application domains: fusion, drug discovery, cardiovascular, materials, migration and climate modelling. There are no ethical concerns regarding the data to be used for fusion, materials or climate modelling. With regard to the remaining domains, we have identified datasets

suitable for our statistical analysis and methods development work in this project which are open and no permission is required for their use.

With regard to the domains in which ethical concerns could arise, the following ones are the sources of data which will be used:

- Drug discovery applications will make use of data from two main sources: clinical datasets made available freely via cBioPortal (http://www.cbioportal.org) and commercial binding assays where the protein sequence is not derived directly from any identifiable individual.
- The migration modelling will exclusively make use of publicly available statistics that are regionally aggregated.
- Cardiovascular applications will make use of pre-existing abstracted models of vascular geometries. The software tools developed under VECMA are designed to be made available to other projects to automate the analyses for which they already have approval.

2.6 Recommendations if appropriate (to the coordinator/ a specific consortium partner) and ethical issues to be followed up

Nothing to recommend.

2.7 Signed approval from the Ethics Advisory Board

Date, place, Name and signature of all members of the EAB

Date	Place	Name	This document
30.11.2018	Brunel University London	Kate Dunbar	Approved
10.12.2018	Hamad Medical Corporation, Qatar	Julien Abi Nahed	Approved

3 Annexes

CV of the EAB President and leader, Dr Julien Abi Nahed

Julien Abinahed, PhD

1 Education
Doctor of Philosophy, PhD ~4.5 years, 2005–2009
Imperial College London, United Kingdom
Department of Computing
Field of study: Computer Vision, Image Processing, Statistical Shape Modeling
Robust Segmentation & Statistical Shape Modeling: Application to Cardiac Imaging
Specialized Master, MSc ~1.5 years, 2003–2004
Ecole Centrale Paris, France
Health Cluster
Specialized postgraduate degree in medical and biotechnological data
Jointly with Gustave Roussy cancer center & Institut d'Optique graduate school
Master of Science, MSc ~5 years, 1998–2003
Université Saint Joseph, Lebanon
Department of Electrical & Mechanical Engineering
5–year general French engineering degree, diplôme d'ingénieur

Specialization in biomedical engineering

2   Experience
Research & Development Executive ~6.5 years, since 2011
Qatar Foundation, Qatar Robotic Surgery Centre, Qatar
Setup and manage R&D team aiming to improve surgical care through technology development and training
Awarded $3.7 million from Qatar National Research Fund Grants
Delivered ~50+ publications
Generated intellectual property, and prototypes
Won local and international awards related to R&D results
Established collaborations with 10+ partners
Presented at several international conferences
Training Executive ~1.3 years, 2009–2010
Qatar Foundation, Qatar Robotic Surgery Centre, Qatar
Development, coordination, and delivery of training programs related to simulation and robotic surgery
Co–delivered training courses related to minimally invasive simulation, and robot–assisted surgery training on *da Vinci* Robot
PhD Candidate ~4.3 years, 2005–2009
Imperial College London, United Kingdom
Research into novel methods to analyze and segment medical images, *i.e.* automatic detection of objects boundaries
Advisors: Professor Guang–Zhong Yang, and Marie–Pierre Jolly
Awarded sponsorship by Siemens Corporate Research as an international student
Teaching assistant, computer vision course for graduate students
Developed segmentation algorithms for extracting the right ventricle from cardiac imaging: Computed Tomography, Magnetic Resonance Imaging, or Ultrasound
Technical Associate ~2.5 years, 2005–2007
Siemens Corporate Research, United States
Development of software prototypes related to medical image analysis
Full–time member of the imaging & visualization department
Participated in developing software modules related to medical image analysis
Generated intellectual property leading to publications and patent
R&D Engineer, Internship ~1 year, 2004–2005
Siemens Corporate Research, United States
Development and testing of algorithms for robust point–matching
Developed software for detecting regions of interest from Ultrasound images
Analyzed and implemented algorithms for robust point–matching
R&D Engineer, Internship ~3 months, 2002
Ecole Nationale Supérieure d'Arts et Métiers, France
Development of control system for applications in biomechanics
Developed and tested control systems for orthopedics using LABVIEW software

3   Languages
Arabic: Native
English: Fluent
French: Fluent
German: Basic

4   Research Interests

My research focuses on the development of methods and solutions to solve unmet needs related to surgery and interventional radiology. Areas of particular interest are (1) medical image computing, (2) surgical/intervention simulation, (3) image–guided intervention/navigation, and (4) robot–assissted surgery/intervention. Clinical applications include urology, surgical oncology, interventional neuroradiology, orthopedics, and cardiac.

Medical Image Computing: extracts clinically–relevant information from high–dimensional anatomical and functional medical images

Surgical/Intervention Simulation: uses virtual reality technology to train clinicians and allows for patient–specific rehearsal of interventions

Image–Guided Intervention: uses medical imaging and navigation to improve treatments

Robot–Assissted Surgery/Intervention: provides tools for safer and accurate interventions, by enhancing the capabilities of clinicians

Keywords: Medical Image Computing, Medical Image Segmentation, Medical Imaging, Computational Anatomy, Computational Physiology, Statistical Shape Modeling, Physics–Based Modeling, Geometric Modeling, Computer Vision, Machine Learning, Statistics, Hi–Fidelity Simulation, Assessment of Surgical Sills, Image–Guided Interventions, Robot–Assisted Interventions

5   Grants and Contracts

$978,000 – Principal Investigator, Qatar National Research Fund – National Priorities Research Program – 5 – 792 – 2 – 328, *CER2EBRAL: Computer Enabled Radiological Resource for Blood flow Rates in Aneurysms using Lattice Boltzmann*, May 2016 to May 2019

$1,000,000 – Principal Investigator, Qatar National Research Fund – National Priorities Research Program – 5 – 995 – 2 – 415, *Development of a Next–Generation Robotic–Assisted Surgery Simulation*, August 2016 to August 2019

$718,000 – Principal Investigator, Qatar National Research Fund – National Priorities Research Program – 9 – 300 – 2 – 132, *A Robotic System for Prostate Interventions with Real–Time MRI Guidance*, January 2017 to January 2020

$1,000,000 – Principal Investigator, Qatar National Research Fund – National Priorities Research Program – 4 – 161 – 2 – 056, *Real–Time Computer Assisted Navigation in Minimally–Invasive Robotic Surgery Using Advanced Multi–Modal Medical Image Based Scene Segmentation, Registration and Visualization*, May 2012 to May 2015

$30,000 – Industry Mentor, Qatar National Research Fund – Undergraduate Research Experience Program – 08 – 014 – 2 – 006, *Parametric Study of Virtual Curvature Recognition: Discrimination Thresholds for Haptic and Visual Sensory Information*, June 2010 to June 2011

6   Invited Presentations

Qatar Robotic Surgery Centre–Modus Operandi, UPESM World Congress, MedTech Institutions Sessions, Canada–Toronto, 2015

Overview of QRSC Research Programs, Université Saint Joseph, Laboratory of Biomechanics and Medical Imaging, Lebanon, 2015

Growing Surgical Research, Hamad Medical Corporation, Qatar, 2015

Qatar Robotic Surgery Centre, Texas A&M University at Qatar, Qatar, 2014

Technology in Surgery, Qatar University, Qatar, 2014

Overview of Surgical Technologies, Université Saint Joseph, Laboratory of Biomechanics and Medical Imaging, Lebanon, 2013

Qatar Robotic Surgery Centre, 3rd North American Summer School on Image-Guided Intervention, Surgical Robotics and Simulation, Canada–Ontario, 2012

Overview of R&D at Qatar Robotic Surgery Centre, Qatar University, Qatar, 2011

Applications of Medical Image Analysis, Université Saint Joseph, faculty of Engineering – ESIB, Lebanon, 2009

7   Advising

Recruited, and managed 4 full–time R&D Scientists

Recruited, and advised 10+ interns over summer, from undergraduate programs at Education City–Qatar Foundation from different universities such as Weill Cornell Medical College in Qatar, Carnegie Mellon University in Qatar, Texas A&M University at Qatar, Virginia Commonwealth University in Qatar, and Qatar University

8   Teaching

Academic

Teaching assistant for Computer Vision course *CO316* for graduate students at Imperial College London, under leadership of Professor Guang–Zhong Yang, 2008

Medical Technologies Workshop, part of course *32414* at Virginia Commonwealth University in Qatar, 2015

Technical Workshops

Ongoing participation in hands-on workshops, Introduction to *da Vinci* Robot, Qatar Robotic Surgery Centre, 2009–2017

Ongoing participation in hands-on workshops, Introduction to Virtual Reality Laparoscopic Simulators, Qatar Robotic Surgery Centre, 2009–2017

9   Professional Service

Committee member

Member of judging panel, CMU-Q Hackathon, 2015

Member of judging panel, Undergraduate Research Experience Program, 2014

Member of the organizing committee, Middle East Conference on Biomedical Engineering, 2014

Member of the program committee, Pumps & Pipes International Conference, 2011

Reviewer

regular reviewer for IEEE Transactions on Medical Imaging

regular reviewer for IEEE Transactions on Information Technology in Biomedicine

regular reviewer for International Conference on Information Processing in Computer-Assisted Interventions

Media coverage

regular press releases related to Qatar Robotic Surgery Centre, from 2010

regular media filming, *e.g.* BBC 4Tech, 2015

CV of the EAB member, Ms Kate Dunbar

106A HIGH STREET ● RUISLIP ● LONDON ● HA4 8LS
Tel: 00447961473850 ● Email: kate.dunbar@ymail.com
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Kate Dunbar

Education and Qualifications

Degree: Law

2001-2004: Keele University, England, United Kingdom

The Law School at Keele scored 5*A in the Research Assessment Exercise (RAE) shortly before I arrived in 2001. This was, at the time, the highest possible score and indicates international excellence throughout the School.

A Levels: Art, English, Psychology
1999-2001: Builth Wells Sixth Form College, Wales, United Kingdom
Art Tutor

10 GCSEs grades A* - C
1995-1999: Llandrindod Wells High School, Wales, United Kingdom
Royal Air Force Training Corps, Duke of Edinburgh Award

Employment Experience
Employer: Brunel University London, 2014 – present
Job Title: Assistant University Secretary (Research Ethics and Governance)

Since my initial employment at Brunel in 2014 I have progressed to a position from which I have effected significant and positive change to the University's research ethics and integrity landscape. Taking over from the former Director of Research Ethics and Governance, I now have esponsibility for delivery of the University's research ethics activities, along with a number of other significant governance responsibilities. During my time in this role I have successfully progressed and enhanced research ethics policy and procedure, resulting in better standards and uniformity of research governance throughout the University. I led the development and implementation of the University's online research ethics application system which is now employed across Brunel and handles in excess of 5,000 submissions per year. I have responsibility for a high level University Committee (the University Research Ethics Committee) which reports directly to the University Council, as well as its sub-committees for oversight of human tissue and live animal experimentation. In this regard, I regularly advise the Chairs and the Committee members on their roles and ensure compliance with evolving statutory and academic obligations as well as national and international regulations and codes of practice. My role involves drafting and review of relevant key University policy as well as monitoring compliance with research ethics and integrity procedures and maintaining positive relationships with other departments and senior members of staff. I provide a focal point for advice relating to matters of research governance and compliance at Brunel and regularly provide guidance and support to staff and students across the University. I deal with allegations of research misconduct and breaches of University regulation on a regular basis. I also work with other UK universities in an advisory capacity with regard to research ethics and integrity policy and procedure.

Employer: Ministry of Justice, 2008 – 2013
Job Title: Clerk to Her Majesty's Judges

As clerk to a High Court Judge for more than five years my job was to provide first line legal support on a one to one basis to ensure efficiency under a tremendous workload and strict deadlines. My duties included legal advice and research, preparing and coordinating trials, assisting with sentencing, attending meetings and high profile social events with and on behalf of the Judge when required. Accuracy and attention to detail were crucial. Based at the Royal Courts of Justice but travelling the country to hear trials of great severity, I was required to act at all times with professionalism, poise and discretion. The role also required a high level of loyalty and commitment and came with a great degree of responsibility.

Employer: World Medical Fund, Malawi, 2007 – 2008
Job Title: Project Coordinator

I enjoyed a challenging role within this international NGO which works mainly with children and young people suffering from HIV/AIDS and malaria in rural East Africa. My duties included providing support

to the medical team, coordinating various projects during campaigning missions and providing administrative support within the office compound.

Employer: Parker Tours, South Africa, 2006 – 2007
Job Title: Project Manager

This was an exciting role within a small British-owned travel company based in South Africa. During my time here I oversaw new business relationships, held regular strategic meetings with the Directors and was solely responsible for research and development, working independently and managing several different aspects of the business concurrently.

Prior to 2006 I lived and worked in a number of countries around the world following my graduation from University. This included work with a hospitality company in South Africa specializing in artistic retreats and time spent working with a marketing team in Vietnam.

Interests & Special Skills:

- I undertake various volunteering roles including as a Samaritans listening volunteer.
- I am very well-travelled and have extensive knowledge of other countries and cultures.
- I have previously taken up skydiving and paragliding. I am a qualified PADI diver.
- I am creative and have a great passion for art.
- I hold a full, clean UK driving license.

References available on request.

CV of the EAB coordinator, Dr Robin Richardson

Dr Robin Archibald RICHARDSON
86 Echline Drive
South Queensferry
EH30 9XG
raarichardson@gmail.com
Mob. (+44) 07910966645

PERSONAL PROFILE
Computational Physicist with extensive experience of developing multiscale applications for High Performance Computing (HPC) platforms. Broad research background spanning parameterisation of force fields for Molecular Dynamics (MD) simulations of Shape
Memory Alloys, Finite Element (FE) simulations of molecular motors in flagella, lattice-Boltzmann simulations of cerebral blood flow, and material properties prediction through coupling of MD with FE (Heterogeneous Multiscale Method).

EDUCATION
University of Leeds, PhD in Computational Biophysics
September 2014, Thesis: "A mesoscale model for coarse-grained protein dynamics"
University of Edinburgh, Master of Physics with (Hons) Computational Physics
Graduated June 2010, First Class

PROFESSIONAL APPOINTMENTS

2015 - Present: Post Doctoral Research Associate (PDRA) at Centre for Computational Science, Dept. of Chemistry, UCL, London.

TECHNICAL SKILLS
Languages C/C++, Fortran, Python, Java
Parallel OpenMP, MPI, Cloud HPC (Docker, Singularity)
Scheduler PBS, LoadLeveler, SLURM, remote submission with Fabric and QCG-Broker
Methods Finite Element, Boundary Element, Lattice Boltzmann, Molecular Dynamics
Visualization Blender, ParaView, VMD, Chimera, PyMOL (plugin development)
Build systems CMake, Make
Collaboration Git, Travis CI

ADMINISTRATIVE ROLES
Screening applications and managing core-hour (and storage) allocations for the ARCHER supercomputer under the CompBioMed project
Member of Programme Committee for the Multiscale and Modelling workshop at ICCS 2019 in Faro, Portugal

TEACHING
Delivering lectures for 3rd year Chemistry courses "Concepts in Computational Chemistry" and "Monte Carlo Methods". Exam question writing and tutorials.
4 years Lab Demonstrator (computational and experimental)

RESEARCH PROJECTS
VECMA (EU, Horizon 2020): Uncertainty quantification in multiscale HPC
COMPAT (EU, Horizon 2020): Computing patterns for multiscale HPC applications
COMPBIOMED (EU, Horizon 2020): Computational models of human organs
CERREBRAL (Qatar National Research Fund): Development and trial of clinical software
UKCOMES (UK, EPSRC): Engineering simulations of mesoscale systems

INTERNSHIPS
Summer 2007: Assistant on research project Observatoire de Haute Provence (France)
Summary: Supervised support work on a PhD project working on the improvement of the treatment of images from the whole sky monitor to estimate the night cloud layer above the Observatory.