

## *Role description of lay panel member for the EVRA Trial Steering Committee (TSC)*

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For further details about this project – please contact the Trial Manager, Francine Heatley [REDACTED]

### *Role Description for:*

Bruce Ley-Greaves, lay member on Steering Group for the EVRA Research Project

### *EVRA Study Summary:*

The EVRA study is for participants who have leg ulcers. A venous leg ulcer is a longstanding (chronic) wound on the leg or foot. These ulcers may either not heal or take a long time to heal and are usually caused by your leg veins not working very well. This problem with the veins is sometimes called varicose veins.

The usual care for venous ulcers is compression bandaging, followed by treatment of the varicose veins once the ulcer has healed. This study is being done to find out whether early treatment (within 2 weeks) of the varicose veins by modern keyhole (endovenous) procedures, in addition to compression bandaging, will help the leg ulcer heal quicker compared to the treatment with compression bandaging alone. Studies have shown that treating varicose veins can reduce the chance of an ulcer coming back, but we do not know if treating the veins early (within 2 weeks) will help your ulcer heal quicker.

### *Purpose of steering group:*

The role of the TSC is to provide advice, through its Chair, to research team on all appropriate aspects of the trial and in particular that the rights, safety and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society.

Other roles include:

- monitoring the progress of the trial, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question
- to ensure appropriate ethical and other approvals are obtained in line with the project plan
- to agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- to provide advice to the investigators on all aspects of the trial

### *The Imperial Research Team:*

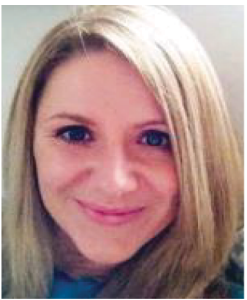
The EVRA Chief Investigator is Professor Alun Davies. The trial manager is Francine Heatley.

#### **Professor Alun Davies:**



Professor Alun Davies Professor of Vascular Surgery at Imperial College London and a Consultant Surgeon whose NHS practice is based at Charing Cross and St Mary's Hospital, London. Professor Davies trained in Cambridge, Oxford, Plymouth, Boston (USA) and Bristol, prior to taking up a Consultant appointment in Charing Cross in 1994. Professor Davies is regarded as a world expert in the management of venous disorder. He has also written extensively on many aspects of vascular disease, writing over 370 peer reviewed manuscripts and runs a large research group.

#### **Francine Heatley, Trial Manager:**



Francine Heatley is a Trial Manager at the UKCRC registered Imperial Clinical Trials Unit (ICTU) in the School of Public Health within the Faculty of Medicine at Imperial College. She is a Biology graduate from the University of Nottingham and has over 10 years' experience of conducting clinical research in therapeutic areas such as vascular surgery, cardiovascular and oncology. She spent 3 years working for an academic research organisation in Canada and is familiar in both Health Canada and FDA clinical trial regulations.

### *Why involve you in the steering committee?*

We are inviting you to be a member of the EVRA as we believe public involvement is an essential part of the development of modern health and social care services. Research that reflects the needs and views of the public is more likely to produce results that can be used to improve health and social care.

### *The TSC Committee Members:*

The TSC chair:

- Professor Julie Brittenden, Chair in Surgery (Clinical)

Other committee members:

- Miss Rebecca Jane Winterborn, Consultant Vascular Surgeon
- Professor Andrea Nelson, Head of School and Professor of Wound Healing
- Dr Richard Haynes, Research Fellow and Honorary Consultant Nephrologist
- Dr Jane Warwick, Statistician, University of Warwick

Other members who may attend the meetings:

- Professor Alun Davies, Chief investigator
- Francine Heatley, Trial Manager
- ICTU Member, Operations Manager
- Sponsor or HTA (funding) representative if requested

### *Confidentiality:*

As a representative of the EVRA trial TSC you are asked not to share confidential information you may have received as a result of your position.

### *Roles and responsibilities of user representative:*

We would like you to:

- To attend the TSC meetings in person or by phone as per your preference
- To represent the patient/lay user views of the EVRA Research Project at other meetings you are asked to attend.
- To contribute to the discussion within the steering group and help us solve any problems we are facing with the study from your perspective.

### *Essential Criteria:*

- Understanding or experience of the issues relating to chronic venous leg ulcers
- Be able to maintain confidentiality
- Have the time to attend meetings

### *Desirable Criteria:*

It would be helpful if you have access to a computer and e-mail and have an understanding of the NHS and research processes

### *Remuneration:*

Travel expenses and out-of-pocket expenses will be reimbursed and refreshments will be provided where appropriate.

## *Support:*

You are able to access support and advice from the Trial manager (contact emails at the top of this document). Please do not hesitate to ask you don't understand something, research is full of acronyms and sometimes we forget to say the terms in full. Further information on Public involvement can be found here:

NIHR HTA Information on lay member reps: <http://www.nets.nihr.ac.uk/ppi>

INVOLVE Information on public involvement in research:

<http://www.invo.org.uk/wp-content/uploads/2011/12/PIP1whatisitallabout.pdf> and a

helpful jargon buster <http://www.invo.org.uk/wp-content/uploads/2011/12/PIP44jargonbuster.pdf>

*Many thanks for contributing to the EVRA research trial we really do appreciate your involvement to help us improve the quality of*

**THANK YOU**