

# EFGCP Annual Conference 2012

## Informed Consent – How Less Could Be More:

Effecting a paradigm shift so we do inform participants

24 & 25 January 2012

Résidence Palace, Brussels, Belgium

*organised by the*

European Forum for Good Clinical Practice



*'where science & ethics meet'*

[conferences@efgcp.eu](mailto:conferences@efgcp.eu) – [www.efgcp.eu](http://www.efgcp.eu)

## Conference Rationale

It has long been recognised by all groups that the information for potential participants is not fit for its purpose – to explain a research study to someone considering whether to join. The current regulations and culture that demand “Information by Volume” do not lead to informed consent.

This practical conference will exchange experience with current innovative ways to improve the information provided, discuss completely new approaches and see how sponsors, researchers and research participants can work together to influence law, policy and ethics and hence change these regulatory requirements and current culture. A report will be written up for wider dissemination.

**It's time for change, but how can we bring this about?**

## Programme Committee

Hugh Davies	National Research Ethics Service, United Kingdom
Genevieve Decoster	IT & GCP Consulting, EFGCP, Belgium
Nicky Dodsworth	Premier Research, United Kingdom
Jan Geissler	Patvocates, EFGCP, Germany
Jozef Glasa	Medical University of Bratislava, EFGCP, Slovakia
Matthew Jones	Johnson & Johnson, United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Marianne Maman	Novartis Pharma, Switzerland
Dominique Sprumont	University of Neuchâtel & TRREE Project, Switzerland
Robrecht Tistaert	PPD, Belgium
Susan Trainor	Trainor and Partners, EFGCP, Belgium
Beat Widler	Clinical QA and Risk Management Expert, Switzerland

## Faculty

Nicola Bedlington	European Patients Forum (EPF), Belgium
Harry Bleiberg	Institut Jules Bordet, Université Libre de Bruxelles, Belgium
Denis Costello	Rare Diseases Europe (EURORDIS), France
Hugh Davies	National Research Ethics Service, United Kingdom
Genevieve Decoster	IT & GCP Consulting, EFGCP, Belgium
Nikos Dedes	European AIDS Treatment Group (EATG), Greece
Nicky Dodsworth	Premier Research, United Kingdom
Christiane Druml	Ethics Committee of the Vienna Medical University, Austria
Gerhard Fortwengel	University of Applied Sciences and Arts, Hannover, Germany
Jan Geissler	Patvocates, EFGCP, Germany
Jozef Glasa	Medical University of Bratislava, EFGCP, Slovakia
Laurence Hugonot	Broca Hospital, France
Piotr Iwanosky	Association for Good Clinical Practice, Poland
Matthew Jones	Johnson & Johnson, United Kingdom

David Kerr	Bournemouth Diabetes and Endocrine Centre, Alliance for European Diabetes Research (EURADIA), United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Petra Knupfer	Landesärztekammer Baden-Württemberg, EFGCP, Germany
Denis Lacombe	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Marianne Maman	Novartis Pharma, Switzerland
Deborah Mascalon	Institute of Genetic Medicine, Italy
Heike Mehrer	Dr. Falk Pharma Freiburg, Germany
Jerry Menikoff	Office for Human Research Protections (OHRP), USA
Detlef Niese	Novartis, Switzerland
Annette Rid	Institute of Biomedical Ethics, University of Zurich, Switzerland
Ian Roberts	London School of Hygiene and Tropical Medicine, United Kingdom
Christopher Roy-Toole	NHS Research Ethics Committee, Barrister, United Kingdom
Michelle Salathé	Swiss Academy of Medical Sciences (SAMS), Switzerland
Heather Sampson	Joint Centre for Bioethics, University of Toronto, Canada
Dominique Sprumont	University of Neuchâtel & TRREE Project, Switzerland
Cristina Torres	Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP), WHO-TDR Clinical Coordination and Training Center (CCTC) Thammasat University (Rangsit Campus), Pathumthani, Thailand
Susan Trainor	Trainor and Partners, EFGCP, Belgium
Rauha Tulkki-Wilke	CRF Health, Finland
Mark Turtle	UK Association of Research Ethics Committees (AREC), United Kingdom
Frank Wells	Advisor to National Research Ethics Service, United Kingdom
Beat Widler	Clinical QA and Risk Management Expert, Switzerland

## Conference Language

The language of the Conference will be English.

## Conference Venue

Résidence Palace – International Press Centre  
Rue de la Loi 155 - 1040 Brussels, Belgium  
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E-mail: [info@residencepalace.be](mailto:info@residencepalace.be) – website: [www.residencepalace.be](http://www.residencepalace.be)

## Registration & Information

E-mail [conferences@efgcp.eu](mailto:conferences@efgcp.eu) or visit [www.efgcp.eu](http://www.efgcp.eu)

## Social Event

On the evening of January 24<sup>th</sup>, all delegates are invited to take part in the Annual Conference social event which is a very special occasion for networking while finding out more about some typical and cultural landmarks of the hosting city, e.g. Brussels in 2012. More details to come soon.

# Agenda

Tuesday, 24 January 2012

- 08:15 Registration and Welcome Coffee  
09:00 Welcome and Introduction to the Conference  
*Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

## PLENARY SESSION 1

### IMPROVING INFORMATION AND EMPOWERING PATIENTS A SHARED RESPONSIBILITY OF SPONSORS, INVESTIGATORS AND PATIENT ORGANISATIONS

Chairpersons: *Jan Geissler, Patvocates, EFGCP, Germany*  
*Detlef Niese, Novartis, Switzerland*

- 09.10 **What do patients want and need to know when participating in a Clinical Trial?**  
*Nikos Dedes, European AIDS Treatment Group (EATG), Greece*
- 09.30 Questions & Discussion
- 09.40 **Is the Patient Information Sheet and Informed Consent Form Protecting the Patient or the Sponsor?**  
*Harry Bleiberg, Institut Jules Bordet, Université Libre de Bruxelles, Belgium*
- 10.00 Questions & Discussion
- 10.10 **The Crucial Role of Oral Information**  
*Petra Knupfer, Landesärztekammer Baden-Württemberg, EFGCP, Germany*
- 10.30 Questions & Discussion
- 10.40 Coffee Break

## PLENARY SESSION 2

### CHANGE IS LONG OVERDUE - BUT HOW DO WE ACHIEVE IT?

Chairpersons: *Jozef Glasa, Medical University of Bratislava, EFGCP, Slovakia*  
*Nicola Bedlington, European Patients Forum (EPF), Belgium*

- 11.00 **Why do we need to reconsider the present Informed Consent process?**  
*Dominique Sprumont, University of Neuchâtel & TRREE Project, Switzerland*
- 11.20 Questions & Discussion

- 11.30 **Why has nothing changed: barriers to change**  
*Denis Lacombe, European Organisation for Research and Treatment of Cancer (EORTC), Belgium*
- 11.50 Questions & Discussion
- 12.00 **Best Practice Example: Which Commands for Informed Consent from the Older People?**  
*Laurence Hugonot, Broca Hospital, France*
- 12.20 Questions & Discussion
- 12.30 **Setting the Scene for the Workshops:**  
**Opportunities for a way out of our problem: developing a risk based approach to seeking consent: ideas from the Roadmap Initiative for Clinical Research in Europe**
- 12.45 Lunch

## WORKSHOPS

### A RISK BASED STRATEGY FOR INFORMED CONSENT: WHAT SHOULD WE PROVIDE FOR?

*Information provided for potential participants is lengthy and difficult to understand or such is the common belief. We ask these workshops to explore informed consent*

- *what are the barriers to change / can a risk based strategy help?*
- *does low risk require different risk/benefit communication?*
- *who should be persuaded of the need to change?*

- 13.45 **Workshop 1: Clinical trials with drugs without marketing authorisation**  
Chair: *Annette Rid, Institute of Biomedical Ethics, University of Zurich, Switzerland*  
Rapporteur: *Mark Turtle, UK Association of Research Ethics Committees (AREC), United Kingdom*
- Workshop 2: Clinical trials with drugs with marketing authorisation, outside their labelled use**  
Chair: *Gerhard Fortwengel, University of Applied Sciences and Arts Hannover, Germany*  
Rapporteur: *Genevieve Decoster, IT & GCP Consulting, EFGCP, Belgium*
- Workshop 3: Clinical trials with drugs with marketing authorisation, within their labelled use**  
Chair: *Michelle Salathé, Swiss Academy of Medical Sciences (SAMS), Switzerland*  
Rapporteur: *David Kerr, Bournemouth Diabetes and Endocrine Centre, Alliance for European Diabetes Research (EURADIA), United Kingdom*
- 15.15 Coffee Break
- 15.45 **Feedback from Workshops 1-3, Panel and Summary of Ideas**  
Chair: *Matthew Jones, Johnson & Johnson, United Kingdom*

## PLENARY SESSION 3

### THE JOSEPH HOET LECTURE ON ETHICS IN CLINICAL RESEARCH

Chairperson: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

16:45 **The Value of Integrity**  
*Frank Wells, Advisor to National Research Ethics Service, United Kingdom*

17:30 EFGCP Annual General Meeting (for EFGCP Members)

18:30 EFGCP Annual Conference Social Event

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## Wednesday, 25 January 2012

08: 00 Welcome Coffee

## PLENARY SESSION 4

### CLINICAL TRIALS IN EMERGENCIES

Chairpersons: *Marianne Maman, Novartis Pharma, Switzerland*  
*Heather Sampson, Joint Centre for Bioethics, University of Toronto, Canada*

08.30 **Clinical Trials in Emergencies: when consent might kill you**  
*Ian Roberts, London School of Hygiene and Tropical Medicine, United Kingdom*

08.50 **A Comparison of EU Member States approaches to Informed Consent in Clinical Trials With Unconscious Patients**  
*Piotr Iwanosky, Association for Good Clinical Practice, Poland*

09.10 **Views from patient representative**  
*Speaker invited*

09.30 **Panel and Open Forum Discussion: Informed Consent Process in Clinical Trials in Emergencies – Experiences and Strategies for Improvement**

Chair: *Christiane Druml, Ethics Committee of the Vienna Medical University, Austria*  
Panellists: *Chairs & Speakers of the Session*  
*Christopher Roy-Toole, NHS Research Ethics Committee, Barrister, United Kingdom*

10.10 Coffee Break

## WORKSHOPS

### NOVEL APPROACHES FOR INFORMED CONSENT

10.30 Workshop 4: **Can technology improve the IC process?**  
Chair: *Rauha Tulkki-Wilke, CRF Health, Finland*  
Rapporteur: *Deborah Mascalzoni, Institute of Genetic Medicine, Italy*

**Workshop 5: The internet and informed consent: the ethical issues and pitfalls - How to address different audiences**

Chair: *Denis Costello, Rare Diseases Europe (EURORDIS), France*  
Rapporteur: *Jan Geissler, Patvocates, EFGCP, Germany*

**Workshop 6: Experiences with national differences in information package constitution**

Chair: *Heike Mehrer, Dr. Falk Pharma Freiburg, Germany*  
Rapporteur: *Nicky Dodsworth, Premier Research, United Kingdom*

12.00 Lunch

13.00 Feedback from Workshops 4-6, Panel and Summary of Ideas  
Key messages from all Workshops

Chair: *Hugh Davies, National Research Ethics Service, United Kingdom*

## PLENARY SESSION 5

### INFORMED CONSENT PROCESS: CONSIDERING THE REGIONS OF THE WORLD WITH THEIR CULTURAL SPECIFIC ASPECTS

Chairpersons: *Beat Widler, Clinical QA and Risk Management Expert, Switzerland*  
*Jerry Menikoff, Office for Human Research Protections (OHRP), USA*

14.00 **Cultural specific aspects of developing countries: understanding in order to improve**  
*Susan Trainor, Trainor and Partners, EFGCP, Belgium*

14.20 Questions & Discussion

14.30 **Changes to the Subject Informed Consent in Federal Common Rule in the USA. How can Europe contribute?**

*Jerry Menikoff, Office for Human Research Protections (OHRP), USA*

14.50 Questions & Discussion

15.00 **What ICH regions can learn from the informed consent process from the developing countries?**

*Cristina Torres, Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP), WHO-TDR Clinical Coordination and Training Center (CCTC) Thammasat University (Rangsit Campus), Pathumthani, Thailand*

15.20 Questions & Discussion

15.30 Coffee Break

## PLENARY SESSION 6

### CONCLUSIONS

16.00 Next steps: a revised summary and comments from delegates  
*Hugh Davies, National Research Ethics Service, United Kingdom*

16.30 Closing Remarks: What is to be done and to whom should we do it?  
*Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

16:45 End of the Conference