EGCP The ICR Ethics & GCP Forum

17th August 2020

The day will start at 09:15 with registration and coffee for a prompt start at 09:45. We aim to finish by 15:50.

ICR Training

EGCP The ICR Ethics & GCP Forum

3 CPD POINTS

17th August 2020

EGCP

Venue - Virtual Forum via Zoom,

Course Outline

Course Information

The Course

The ICR Ethics and GCP Forum provides an excellent opportunity to:

- Keep up to date with current ethical and clinical research issues
- Learn about new industry and regulatory initiatives
- Hear key industry figures speak about their specialist fields
- Network with fellow clinical research professionals

09:30 Online Registration

10:00 Welcome

Ethics Forum

10:10 MHRA Update
Kirsty Wydenbach, Deputy Unit Manager / Senior Medical Assessor, MHRA Clinical Trials Unit

11:00 Pause

11:10 Compliance in Home Research Nursing

Natalia Janik, Quality Assurance Manager
Illingworth Research Group Limited

12:00 Lunch Break

GCP Forum – Patient Participation

13.00 NIHR Interactive Costing Tool
Phil Good, National Study Startup Manager
NIHR Coordinating Centre

13:50 Pause

14:00 Update on HRA Approval and HRA Activity

Janet Messer, Director of Approvals Service, HRA

14:50 Pause

15:00 Key GCP Updates
A summary of changes in GCP-related regulations and guidelines since the last Ethics/GCP Forum meeting
GCP Steering Committee

15:50 Close

Learning Objectives

Ethics Forum Chair: Joan Perou

GCP Forum Steering Committee:

- Helen Buck,
- Janice Hedgecock,
- Stuart Harris,
- Julia DeCesare
- Heidi Chandler

UCL Joint Research Office:
Helen Cadiou

Who would benefit

Course Fees

Guest	**£60.00**
ICR Member	**£45.00**
ICR Member Academic	**£45.00**

Your Trainers

Kirsty Wydenbach

Dr Kirsty Wydenbach is a Senior Medical Assessor and the Deputy Unit Manager in the Clinical Trials Unit, having joined the MHRA in 2009. She has been involved in the UK regulation of clinical trials across all therapy areas and all phases of development, including trials for chemical and biological products, Advanced Therapy Products and many first-in-man studies. She has also been involved in European discussions aiming to establish an EU harmonised approach to clinical trials, particularly for Developmental Safety Update Reports (DSURs) and Reference Safety Information (RSI). She was also an EMA expert for the update of the First-in-Human guideline.

More recent EU priorities have included the new Clinical Trial Regulation and Kirsty currently sits on the safety subgroup of the Clinical Trials Facilitation Group (CTFG) that is working on how safety reporting aspects will be implemented. Other recent work has included collaboration with external industry groups and regulators regarding adaptive and novel trial designs: she is leading on this aspect for the MHRA in order to implement that aspect of the Life Sciences Industrial Strategy, and was a contributor to the EU CTFG "Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials".

Your Trainers

Janet Messer

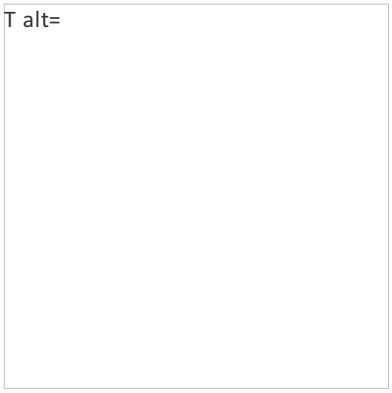
Dr Janet Messer

Janet Messer is Director of Approvals Service at the Health Research Authority. She is responsible for the Research Ethics, Confidentiality Advice, Assessment and Assurance services, alongside the supporting guidance, advice and learning functions. Her team works collaboratively with a wide range of partner organisations to fulfil the HRA's aims to make it easier to do good quality ethical research in the UK. She has a PhD in biochemistry from University of Cambridge and a Masters in Medical Law, along with many years' experience of clinical research in the pharmaceutical industry, NHS R&D and the NIHR Clinical Research Network.

She sits on the NHS Digital Research Advisory Group and is a member of its ethics & streamlining working group. She has presented internationally on use of patient data and the General Data Protection Regulation.

Your Trainers

Heidi Chandler



Pre-Course Questionnaire - To be completed by all delegates

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Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: EGCP The ICR Ethics & GCP Forum

Date: 17 August 2020

Name: .....

Company / Hospital: .....

Position / Job Title: .....

How much experience of clinical trials do you have? (Years)

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What are you hoping to get out of the day?

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State one issue/problem you would like discussed at the meeting

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Special Dietary Requirements

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* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

Training Location

Address: Virtual Forum via Zoom,

Local Taxi Companies

Accommodation

The ICR does not specifically recommend any accommodation - however the following are within easy travelling distance of the training venue

There are also a number of travel websites which may allow you to identify local accommodation and special offers - e.g. expedia

The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free – however it is not possible to cover all possible requests for dietary preferences.

Registration Form

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: EGCP The ICR Ethics & GCP Forum **Course Date:** 17 August 2020

Membership No.: ..... **Title(Dr,Mr,Mrs,etc):** ..... **First Name:** .....

Surname: ..... **Job Title:** .....

Company Name: .....

Email Address: .....

Confirmation of booking will be sent by email, unless you request here that it is sent by post ☐

Correspondence Address

Address: .....

Postcode: ..... **Country:** ..... **Telephone Number:** .....

Special Dietary Requirements

.....

Declaration

I agree to the terms and conditions of booking **Signature:** .....

Method of Payment

Please not that your place will only be confirmed when payment has been received (please tick as required)

I wish to pay the fee of .....

☐ I enclose a cheque payable to "The Institute of Clinical Research"

OR

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Start Date ☐☐ ☐☐ **Expiry Date** ☐☐ ☐☐

Name (as it appears on the card) .....

Signature of card holder .....

OR

☐ Please invoice my company using Purchase Order Number ☐ Invoices can only be raised when a PO no. is provided

Correspondence Address

Address: .....

Postcode: ..... **Country:** .....