

SECOND INSUBRIA INTERNATIONAL SCHOOL on METHODOLOGY, ETHICS and INTEGRITY in BIOMEDICAL RESEARCH

Promoting responsible conduct of biomedical research

12th-16th November 2018 University of Insubria



PROGRAM of the SCHOOL

Under the Auspices of:



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Organizing Secretariat

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PROGRAM of the SCHOOL

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SPEAKERS & CHAIRS Walter AGENO - University of Insubria, Varese (I)

Rita BANZI - IRCCS Istituto di Ricerche Mario Negri, Milan (I)

Francesco BARONE-ADESI - University of Eastern Piedmont, Novara (I) Fabio BLANDINI - IRCCS Mondino Foundation, Neurological Institute, Pavia (I) **Lex BOUTER** - Amsterdam University Medical Centers, Amsterdam (NL) Paolo CATTORINI - University of Insubria, Varese (I) Marco COSENTINO - University of Insubria, Varese (I) **Gillian CURRIE** - University of Edinburgh, CAMARADES (SCO) Francesco DENTALI - University of Insubria, Varese (I) Alice FABBRI - University of Sidney, Sidney (AU) Marco FERRARI - University of Insubria, Varese (I) Franca MARINO - University of Insubria, Varese (I) Mario PICOZZI - University of Insubria, Varese (I) Gian Marco PODDA - University of Milan, Milan (I) **Domenico PRISCO** – University of Florence, Florence (I) **Corinna RAIMONDO** - Northwestern University, Chicago (USA) **Emanuela RASINI** - University of Insubria, Varese (I) **Laura RIBEIRO** - University of Porto, Porto (P) Silvia SCALZINI - Università LUISS Guido Carli, Rome (I) Alessandro SQUIZZATO - University of Insubria, Varese (I)



SCIENTIFIC COMMITTEE

Loreta TAUGINIENĖ - Mykolas Romeris University, Vilnius (LT)

Marco Cosentino - Franca Marino - Mario Picozzi Walter Ageno - Alessandro Squizzato

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TopicsAT A GLANCE







COURSE PROGRAM

Topics

Module #1 - RESEARCH INTEGRITY

Coordinator: Marco Cosentino

name	surname	title	duration (hours)	module	date	time
Lex	BOUTER	Fostering responsible research practices	1	1.1	12	09.00-10.00
Marco	COSENTINO	Integrity and misconduct in biomedical research: a primer	1	1.2	12	10.00-11.00
Laura	RIBEIRO	Teaching ethics to the young generation of biomedical researchers: bridging the gap between theory and practice	2	1.3	12	11.00-13.00
Loreta	TAUGINIENĖ	Science and Society – what role should a scientist have in these days?	2	1.4	12	14:00-16:00
Corinna	RAIMONDO	Research Integrity: a US perspective	1	1.5/1	14	17.00-18.00
Corinna	RAIMONDO	Research Integrity: a US perspective	2	1.5/2	15	16.00-18.00
Alice	FABBRI	Understanding and dealing with conflicts of interest in biomedical research	2	1.6	13	9.00-11.00

	Day #1	Day #2	Day #3	Day #4	Day #5
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4
12:00-13:00	107	2.1	3.3	4.0	(2,5 ore)
14:00-15:00	1.4	2.3		4.4	5.1
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1
16:00-17:00	2.4	2.2		1.5/2	5.2
17:00-18:00	2.4	2.2	1.5/1	1.3/4	5,2

Topics

Module #2 - PRECLINICAL RESEARCH AND LABORATORY ANIMAL CARE AND USE

Coordinator: Franca Marino

name	surname	title	duration (hours)	module	date	time
Franca	MARINO	Organization and management of the working environment in biomedical research laboratories	2	2.1	13	11.00-13.00
Emanuela	RASINI	Responsible data management in biomedical research	2	2.2	13	16.00-18.00
Gillian	CURRIE	Increasing value in animal research: a focus on experimental design and reproducibility	2	2.3	13	14.00-16.00
Fabio	BLANDINI	A critical review of the use of animal models in neurological research	2	2.4	12	16.00-18.00

	Day #1	Day #2	Day #3	Day #4	Day #5
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4
12:00-13:00	1.5	4.1	3.3	Tio	(2,5 ore)
14:00-15:00	1.4	2.3		4.4	5.1
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	3.1
16:00-17:00	2.4	2.2		1.5/2	5.2
17:00-18:00	2.4	2.2	1.5/1	1.5/2	3.4

Topics

Module #3 - HUMAN SUBJECT RESEARCH AND INSTITUTIONAL REVIEW BOARDS

Coordinator: Mario Picozzi

name	surname	title	duration (hours)	module	date	time
Mario	PICOZZI	Integrità ed etica nella ricerca: il ragionamento etico e il ruolo del comitato etico	2	3.1	14	9.00-11.00
Francesco	BARONE- ADESI	Methodology issues in epidemiological research	1,5	3.2	14	14.00-15.30
Silvia	SCALZINI	The impact of the new EU General Data Protection Regulation on Biomedical Research: a comparative perspective	1,5	3.3	14	15.30-17.00
Marco	FERRARI	Responsible research practice in pharmacogenetic studies	1,5	3.4	16	9.00-10.30
Paolo	CATTORINI	Farmaci, etica e cinema	2	3.5	14	11.00-13.00

	Day #1	Day #2	Day #3	Day #4	Day #5
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4
10:00-11:00	1.2	1.0	3.1 4.1/4.2		(1,5 ore)
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4
12:00-13:00	1.5	2.1	3.3	4.0	(2,5 ore)
14:00-15:00	1.4	2.3		4.4	5.1
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	3.1
16:00-17:00	2.4	2.2		1.5/2	5.2
17:00-18:00	2.4	6.2	1.5/1	1.3/2	3.2

Topics

Module #4 - PUBLISH OR PERISH Coordinator: Walter Ageno

name	surname	title	duration (hours)	module	date	time
Walter	AGENO	What are scientific publications? - The peer review process	1	4.1	15	9.00-10.00
Walter	AGENO	The International Committee of Medical Journal Editors (ICMJE) and guidelines to report a scientific study - Case study: Analysis of the editorial process of selected manuscripts	1	4.2	15	10.00-11.00
Domenico	PRISCO	The publication process, the scientific publications global market, open access journals	2	4.3	15	11.00-13.00
Marco	COSENTINO	Bibliometrics (is) for dummies! Use, misuse and abuse of citations (and other biases)	1	4.4	15	14.00-15.00

	Day #1	Day #2	Day #3	Day #4	Day #5
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4
10:00-11:00	1.2	1.0	3.1 4.1/4.2		(1,5 ore)
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4
12:00-13:00	1.5	2.1	3.3	4.0	(2,5 ore)
14:00-15:00	1.4	2.3		4.4	5.1
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	3.1
16:00-17:00	2.4	2.2		1.5/2	5.2
17:00-18:00	2.4	6.2	1.5/1	1.3/2	3.2

Topics

Module #5 - UNDERSTANDING BIOMEDICAL RESEARCH PAPERS

Coordinator: Alessandro Squizzato

name	surname	title	duration (hours)	module	date	time
Alessandro	SQUIZZATO	Reading and understanding preclinical and clinical papers	2	5.1	16	14.00-16.00
Gian Marco	PODDA	Observational research. Case reports and case series, are they useful, yet? Case control and cohort studies - Interventional studies: why and how to deal with it?	2	5.2	16	16.00-18.00
Rita	BANZI	Narrative and systematic revisions of the literature, meta-analysis and guidelines: which should we choose and why? Anything else? Where can I look for evidence? Main databases, Medical Subjects Headings, Boolean language and search strategies	2,5	5.3/5.4	16	10.30-13.00
Francesco	DENTALI	P, type I error, statistical significance, confidence intervals, relative risk vs absolute risk and quality - Non inferiority, equivalence and superiority: what's in a word?	1	5.5	15	15.00-16.00

	Day #1	Day #2	Day #3	Day #4	Day #5
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4
12:00-13:00	113	2.1	5.3	Tio	(2,5 ore)
14:00-15:00	1.4	2.3		4.4	5.1
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1
16:00-17:00	2.4	2.2		1.5/2	5.2
17:00-18:00	2.4	4.4	1.5/1	1.3/2	5.2



Timetable AT A GLANCE



name	surname	title	(hours)	module	date	time
Lex	BOUTER	Fostering responsible research practices	1	1.1	12	09.00-10.00
Marco	COSENTINO	Integrity and misconduct in biomedical research: a primer	1	1.2	12	10.00-11.00
Laura	RIBEIRO	Teaching ethics to the young generation of biomedical researchers: bridging the gap between theory and practice	2	1.3	12	11.00-13.00
Loreta	TAUGINIENĖ	Science and Society – what role should a scientist have in these days?	2	1.4	12	14:00-16:00
Fabio	BLANDINI	A critical review of the use of animal models in neurological research	2	2.4	12	16.00-18.00
Alice	FABBRI	Understanding and dealing with conflicts of interest in biomedical research	2	1.6	13	9.00-11.00
Franca	MARINO	Organization and management of the working environment in biomedical research laboratories	2	2.1	13	11.00-13.00
Emanuela	RASINI	Responsible data management in biomedical research	2	2.2	13	16.00-18.00
Gillian	CURRIE	Increasing value in animal research: a focus on experimental design and reproducibility	2	2.3	13	14.00-16.00
Corinna	RAIMONDO	Research Integrity: a US perspective	1	1.5/1	14	17.00-18.00
Mario	PICOZZI	Integrità ed etica nella ricerca: il ragionamento etico e il ruolo del comitato etico	2	3.1	14	9.00-11.00
Francesco	BARONE- ADESI	Methodology issues in epidemiological research	1,5	3.2	14	14.00-15.30
Silvia	SCALZINI	The impact of the new EU General Data Protection Regulation on Biomedical Research: a comparative perspective	1,5	3.3	14	15.30-17.00
Paolo	CATTORINI	Farmaci, etica e cinema	2	3.5	14	11.00-13.00
Corinna	RAIMONDO	Research Integrity: a US perspective	2	1.5/2	15	16.00-18.00
Walter	AGENO	What are scientific publications? - The peer review process	1	4.1	15	9.00-10.00
Walter	AGENO	The International Committee of Medical Journal Editors (ICMJE) and guidelines to report a scientific study - Case study: Analysis of the editorial process of selected manuscripts	1	4.2	15	10.00-11.00
Domenico	PRISCO	The publication process, the scientific publications global market, open access journals	2	4.3	15	11.00-13.00
Marco	COSENTINO	Bibliometrics (is) for dummies! Use, misuse and abuse of citations (and other biases)	1	4.4	15	14.00-15.00
Francesco	DENTALI	P, type I error, statistical significance, confidence intervals, relative risk vs absolute risk and quality · Non inferiority, equivalence and superiority: what's in a word?	1	5.5	15	15.00-16.00
Marco	FERRARI	Responsible research practice in pharmacogenetic studies	1,5	3.4	16	9.00-10.30
Alessandro	SQUIZZATO	Reading and understanding preclinical and clinical papers	2	5.1	16	14.00-16.00
Gian Marco	PODDA	Observational research. Case reports and case series, are they useful, yet? Case control and cohort studies - Interventional studies: why and how to deal with it?	2	5.2	16	16.00-18.00
Rita	BANZI	Narrative and systematic revisions of the literature, meta-analysis and guidelines: which should we choose and why? Anything else? Where can I look for evidence? Main databases, Medical Subjects Headings, Boolean language and search strategies	2,5	5.3/5.4	16	10.30-13.00



Timetable

Day #1 - 12 November 2018

name	surname	title	duration (hours)	module	date	time
Lex	BOUTER	Fostering responsible research practices	1	1.1	12	09.00-10.00
Marco	COSENTINO	Integrity and misconduct in biomedical research: a primer	1	1.2	12	10.00-11.00
Laura	RIBEIRO	Teaching ethics to the young generation of biomedical researchers: bridging the gap between theory and practice	2	1.3	12	11.00-13.00
Loreta	TAUGINIENĖ	Science and Society – what role should a scientist have in these days?	2	1.4	12	14:00-16:00
Fabio	BLANDINI	A critical review of the use of animal models in neurological research	2	2.4	12	16.00-18.00

	Day #1	Day #2	Day #3	Day #4	Day #5	
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4	
10:00-11:00	1.2	1.0	9.1	4.1/4.2	(1,5 ore)	
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4	
12:00-13:00	***	2.1		T.0	(2,5 ore)	
14:00-15:00	1.4	2.3		4.4	5.1	
15:00-16:00	II.	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	3.1	
16:00-17:00	2.4	2.2		1.5/2	5.2	
17:00-18:00	2.1	2.2	1.5/1	1.3/2	3.2	

Timetable

Day #2 - 13 November 2018

name	surname	title	duration (hours)	module	date	time
Alice	FABBRI	Understanding and dealing with conflicts of interest in biomedical research	2	1.6	13	9.00-11.00
Franca	MARINO	Organization and management of the working environment in biomedical research laboratories	2	2.1	13	11.00-13.00
Emanuela	RASINI	Responsible data management in biomedical research	2	2.2	13	16.00-18.00
Gillian	CURRIE	Increasing value in animal research: a focus on experimental design and reproducibility	2	2.3	13	14.00-16.00

	Day #1	Day #2	Day #3	Day #4	Day #5	
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4	
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)	
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4	
12:00-13:00	107	2.1	3.3	4.0	(2,5 ore)	
14:00-15:00	1.4	2.3		4.4	5.1	
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1	
16:00-17:00	2.4	2.2		1.5/2	5.2	
17:00-18:00	2.4	2.2	1.5/1	1.3/4	3(2)	

Timetable

Day #3 - 14 November 2018

name	surname	title	duration (hours)	module	date	time
Corinna	RAIMONDO	Research Integrity: a US perspective	1	1.5/1	14	17.00-18.00
Mario	PICOZZI	Integrità ed etica nella ricerca: il ragionamento etico e il ruolo del comitato etico	2	3.1	14	9.00-11.00
Francesco	BARONE- ADESI	Methodology issues in epidemiological research	1,5	3.2	14	14.00-15.30
Silvia	SCALZINI	The impact of the new EU General Data Protection Regulation on Biomedical Research: a comparative perspective	1,5	3.3	14	15.30-17.00
Paolo	CATTORINI	Farmaci, etica e cinema	2	3.5	14	11.00-13.00

	Day #1	Day #2	Day #3	Day #4	Day #5	
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4	
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)	
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4	
12:00-13:00	107	2.1	3.3	4.5	(2,5 ore)	
14:00-15:00	1.4	2.3		4.4	5.1	
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1	
16:00-17:00	2.4	2.2		1.5/2	5.2	
17:00-18:00	2.4	2.2	1.5/1	1.3/2	5.2	



Timetable

Day #4 - 15 November 2018

name	surname	title	duration (hours)	module	date	time
Corinna	RAIMONDO	Research Integrity: a US perspective	2	1.5/2	15	16.00-18.00
Walter	AGENO	What are scientific publications? - The peer review process	1	4.1	15	9.00-10.00
Walter	AGENO	The International Committee of Medical Journal Editors (ICMJE) and guidelines to report a scientific study - Case study: Analysis of the editorial process of selected manuscripts	1	4.2	15	10.00-11.00
Domenico	PRISCO	The publication process, the scientific publications global market, open access journals	2	4.3	15	11.00-13.00
Marco	COSENTINO	Bibliometrics (is) for dummies! Use, misuse and abuse of citations (and other biases)	1	4.4	15	14.00-15.00
Francesco	DENTALI	P, type I error, statistical significance, confidence intervals, relative risk vs absolute risk and quality - Non inferiority, equivalence and superiority: what's in a word?	1	5.5	15	15.00-16.00

	Day #1	Day #2	Day #3	Day #4	Day #5	
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4	
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)	
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4	
12:00-13:00	107	2.1	3.3	4.5	(2,5 ore)	
14:00-15:00	1.4	2.3		4.4	5.1	
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1	
16:00-17:00	2.4	2.2		1.5/2	5.2	
17:00-18:00	2.4	2.2	1.5/1	1.3/2	5.2	

COURSE PROGRAM

Timetable

Day #5 - 16 November 2018

name	surname	title	duration (hours)	module	date	time
Marco	FERRARI	Responsible research practice in pharmacogenetic studies	1,5	3.4	16	9.00-10.30
Alessandro	SQUIZZATO	Reading and understanding preclinical and clinical papers	2	5.1	16	14.00-16.00
Gian Marco	PODDA	Observational research. Case reports and case series, are they useful, yet? Case control and cohort studies - Interventional studies: why and how to deal with it?	2	5.2	16	16.00-18.00
Rita	BANZI	Narrative and systematic revisions of the literature, meta-analysis and guidelines: which should we choose and why? Anything else? Where can I look for evidence? Main databases, Medical Subjects Headings, Boolean language and search strategies.	2,5	5.3/5.4	16	10.30-13.00

	Day #1	Day #2	Day #3	Day #4	Day #5	
09:00-10:00	1.1	1.6	3.1	4.1/4.2	3.4	
10:00-11:00	1.2	1.0	3.1	4.1/4.2	(1,5 ore)	
11:00-12:00	1.3	2.1	3.5	4.3	5.3/5.4	
12:00-13:00	1.3	2.1	3.3	4.5	(2,5 ore)	
14:00-15:00	1.4	2.3		4.4	5.1	
15:00-16:00	1.4	2.3	3.2/3.3 (1,5 + 1,5 ore)	5.5	5.1	
16:00-17:00	2.4	2.2		1.5/2	5.2	
17:00-18:00	2.4	4.4	1.5/1	1.5/2	5.2	



SPEAKERS & CHAIRS

Biosketches



Walter Ageno - University of Insubria, Varese I)

Professore di Medicina Interna e Direttore della Scuola di Specializzazione in Medicina d'Emergenza e Urgenza e del Centro Ricerche sulle malattie tromboemboliche e le terapie antitrombotiche dell'Università dell'Insubria. Autore di oltre 450 articoli in extenso indicizzati su MEDLINE, di linee guida nazionali e internazionali sul tromboembolismo venoso e sulle terapie anticoagulanti e di 21 capitoli di libri in tema di patologie vascolari e di trombosi venose e arteriose. Coordinatore di studi multicentrici nazionali e internazionali su patologie tromboemboliche e farmaci antitrombotici, componente di steering committee e adjudication committee in studi nazionali e internazionali sulla prevenzione eil trattamento del tromboembolismo venoso. Deputy editor per la rivista Thrombosis and Haemostasis, associate editor per le riviste Blood Transfusion, Monaldi Archive for Chest Disease e Internal and Emergency Medicine, componente del board editoriale delle riviste Journal of Thrombosis and Haemostasis, Vascular Medicine e Clinical and Experimental Thrombosis and Haemostasis.



Rita Banzi - IRCCS Istituto di Ricerche Mario Negri, Milan (I)

Farmacologo clinico e dottore di ricerca in scienze farmaceutiche. Attualmente responsabile del Centro di Politiche Regolatorie del Farmaco presso l'istituto Mario Negri di Milano dove si occupa della valutazione critica della metodologia della ricerca clinica, della legislazione e delle politiche farmaceutiche e della trasparenza nella ricerca. Collabora stabilmente con il Dipartimento di Scienze Biomediche per la Salute dell'Università di Milano nell'organizzazione di corsi di perfezionamento in studi randomizzati, revisioni sistematiche e linee guida. Partecipa a progetti di produzione di revisioni sistematiche ed è stata coinvolta in gruppi metodologici per la preparazione di linee guida. Ha prestato servizio presso l'Agenzia italiana del farmaco nel 2006-2007 e presso il Centro Cochrane Italiano dal 2007 al 2010. Dal 2010 al 2014 è stata contact point per l'Italia dell'infrastruttura europea di supporto alla pianificazione e conduzione di studi clinici accademici multinazionali (ECRIN).



Francesco Barone Adesi - University of Eastern Piedmont, Novara (I)

Associate professor of public health, graduated in medicine at the Catholic University of Sacred Heart in Rome and specialized in occupational medicine and in medical statistics. He holds a PhD in environmental medicine. His research interests include pharmacoepidemiology, evaluation of public health interventions, occupational and environmental epidemiology, statistical methods for epidemiology and public health, systematic reviews and meta-analyses. His research has been awarded by the National Institutes of Health and the European Society of Cardiology. He is member of the Board of the Italian Epidemiological Association (AIE).



Fabio Blandini - IRCCS Mondino Foundation, National Neurological Institute, Pavia (I)

MD with specializations in neurology and biochemistry and clinical chemistry. Dr. Blandini is currently Scientific Director of the IRCCS Mondino Foundation, a research hospital dedicated to neurological diseases, funded by the Italian Ministry of Health. He is member of the Pan-Europen Committee of the International Brain Research Organization (IBRO) and IBRO delegate at the European Brain Council board. He is member of the editorial boards of various journals (Neurobiology of Disease, Scientific reports, Frontiers in Cellular Neuroscience, Frontiers in Neuroanatomy, Functional Neurology). He is also part of the Ethics Committee for human experimentation of the S. Matteo/Mondino hospitals (Pavia). In the past 20 years, dr. Blandini's research activity has been centred on the pre-clinical investigation of the pathogenesis and pathophysiology of Parkinson's disease, with a specific interest in the role of experimental models.



Lex Bouter - Amsterdam University Medical Centers, Amsterdam (NL)

Professor Lex M Bouter, PhD, has a tenured chair in Methodology and Integrity at the Department of Epidemiology and Biostatistics of the VU University Medical Centre in Amsterdam. Before taking up the current position he was professor of Epidemiology and Rector of the Vrije Universiteit Amsterdam. In 1988 he published a textbook on epidemiology, the seventh revised Dutch edition of which appeared in 2016 and the first English edition in 2018. Lex Bouter has a keen interest in clinimetrics and systematic reviews. He is a member of the Steering Committee of the REWARD (REduce research Waste And Reward Diligence) Alliance. He is currently mainly involved in teaching and research regarding responsible conduct of research, questionable research practices and research misconduct. In 2017 he organized and co-chaired the 5th World Conference on Research Integrity in Amsterdam and became chair of the World Conferences on Research Integrity Foundation. Lex Bouter has supervised 74 PhD students, of whom to date 15 were appointed as professor. Personal page: https://research.vu.nl/en/persons/lm-bouter





Paolo Cattorini - University of Insubria, Varese (I)

Professore ordinario di Medicina Legale, Università degli Studi dell'Insubria, Docente di Bioetica. Già componente del Comitato Nazionale per la Bioetica.



Marco Cosentino - University of Insubria, Varese (I)

Professor of Medical Pharmacology since 2001, Marco Cosentino is currently Director of the Center for Research in Medical Pharmacology and Director of the School of Medical Pharmacology. He has been Coordinator of the PhD program in Experimental and Clinical Medicine and Medical Humanities and Coordinator of the graduate School on Methodology, Ethics and Integrity in Biomedical Research. He served in several Ethics Committees for human and animal experimental research and contributed to writing the Academic Ethics Code of the University of Insubria. Prof. Cosentino is co-responsible for teaching research integrity issues to PhD students and early stage researchers as well as for optional seminars for medical students about integrity and conflict of interest in biomedical research. Prof. Cosentino is delegate for the University of Insubria to the ENAI - European Network for Academic Integrity (https://www.academicintegrity.eu/) and local coordinator for the Horizon 2020 project 'Virtue-based ethics and integrity of research: Train-the-trainer programme for upholding the principles and practices of the European Code of Conduct for Research Integrity' (VIRT2UE).



Gillian Currie - University of Edinburgh, CAMARADES (SCO)

Gillian Currie is a Postdoctoral Researcher in the CAMARADES group at the University of Edinburgh interested in the validity and reproducibility of preclinical research. Gillian studied Pharmacology at honours level and gained a PhD investigating novel analgesics in animal models of bone cancer pain. She applies the techniques of systematic review and meta-analysis to analyse data from animal studies modelling diseases, with a particular interest in animal models of neuropathic pain. The empirical evidence from this work is being used to drive improvements in preclinical research; informing experimental design and investigating the risk of bias on reported outcomes.



Francesco Dentali - University of Insubria, Varese (I)

Medico chirurgo specialista in Medicina Interna, già Clinical Research Fellow in Ematologia, presso la Faculty of Health Sciences, McMaster University, Hamilton, Canada (2004-2005). Professore Associato in Medicina Interna all'Università dell'Insubria di Varese (2014-). Direttore della S.C. di Medicina Generale e Cure Subacute, Ospedale Luini Confalonieri, Luino (2017-). Direttore del Dipartimento di Ricerca della Società Scientifica FADOI. Autore principale o coautore di oltre 280 pubblicazioni per esteso in riviste internazionali e nazionali, di oltre 100 abstracts presentati a congressi nazionali ed internazionali e di capitoli di testi di Trombosi ed Emostasi. Autore principale o co-autore Relatore in oltre 100 congressi nazionali ed internazionali. Membro dell'advisory board della rivista internazionale Journal of Thrombosis and Haemostasis. Revisore per numerose riviste internazionali. Co-autore di Linee Guida Internazionali (SISET 2009, ACCP 2012, ESO 2017).



Alice Fabbri - University of Sidney (AU)

Alice Fabbri è un medico specialista in Igiene e Medicina Preventiva. Nel 2017 ha conseguito il Dottorato di Ricerca in Medicia Clinica e Sperimentale e Medical Humanities presso l'Università dell'Insubria e lavora attualmente presso l'Università di Sydney dove si occupa di ricerca su politiche farmaceutiche e conflitto d'interessi in salute.



Marco Ferrari - University of Insubria, Varese (I)

Graduated in Biological Sciences (University of Milano, Italy, 1995), qualification in Pharmacology (University of Pavia, Italy, 2001) and PhD in Pharmacology (University of Insubria, Italy 2009). From 2006, Assistant Professor in Pharmacology at the University of Insubria. From 2004 to 2013 member of Ethics Committees for Human Research of the Ospedale Sant'Anna, Como Italy. 2011-date teacher and expert component of PhD course in Experimental and Clinical Medicine and Medical Humanities of the University of Insubria. 2013-date Member Commission Guidance of the University of Insubria.







Franca Marino - University of Insubria, Varese (I)

Professor of Medical Pharmacology, Franca Marino has been coordinator of the PhD program in Clinical and Experimental Pharmacology, member of the Faculty of the PhD program in Experimental and Clinical Medicine and Medical Humanities and member of the scientific committee of the graduate School on Methodology, Ethics and Integrity in Biomedical Research at the UNINS. Prof. Marino is a member of ENAI - European Network for Academic Integrity (https://www.academicintegrity.eu/) and involved in the Horizon 2020 project 'Virtue-based ethics and integrity of research: Train-the-trainer programme for upholding the principles and practices of the European Code of Conduct for Research Integrity' (VIRT2UE).



Mario Picozzi - University of Insubria, Varese (I)

Mario Picozzi is Professor of Forensic Medicine and Clinical Bioethics at the University of Insubria. He graduated in medicine at the University of Milan in 1991 and obtained the specialization in Forensic Medicine at the University of Insubria in 2002. He has been member of the scientific committee of the International Master in Medical Humanities, University of Insubria. Prof. Picozzi served in several Ethics Committees for human and animal experimentation. He is currently member of the Faculty of the PhD program in Experimental and Clinical Medicine and Medical Humanities, and member of the scientific committee of the graduate School on Methodology, Ethics and Integrity in Biomedical Research at the University of Insubria. He contributed to writing the Academic Ethics Code of the University of Insubria and is presently member of the Academic Ethics Committee. Prof. Picozzi is a member of ENAI - European Network for Academic Integrity (https://www.academicintegrity.eu/) and involved in the Horizon 2020 project 'Virtue-based ethics and integrity of research: Train-the-trainer programme for upholding the principles and practices of the European Code of Conduct for Research Integrity' (VIRT2UE).



Gian Marco Podda - University of Milan (I)

MD PhD, is a clinician who works in Internal Medicine Word, at San Paolo Hospital, ASST Santi Paolo e Carlo, University of Milan, Italy. Dr. Podda has author and co-authored numerous articles indexed in Medline and abstract presented at national and international meetings; he was co-organizer of the European School of Internal Medicine of the European Federation of Internal Medicine and of Italian Society of Internal Medicine. The main fields of interest are primary haemostasis and evidence-based medicine.



Domenico Prisco - University of Florence (I)

Laureato in Medicina e Chirurgia nell'Università degli studi di Firenze, specializzato in Medicina Interna e in Ematologia, è attualmente professore ordinario di Medicina Interna e presidente del corso di laurea in Medicina e Chirurgia presso l'Università degli Studi di Firenze e direttore della SOD complessa di Medicina Interna Interdisciplinare, Azienda Ospedaliero- Universitaria Careggi, Firenze. Autore di oltre 350 articoli e rassegne scientifiche su Giornali prevalentemente Internazionali sui temi della fisiopatologia degli stati trombofilici, delle terapie antitrombotiche e le malattie autoimmunitarie sistemiche ad interessamento vascolare. E' stato membro del Comitato Esecutivo della Società Italiana per lo Studio dell'Emostasi e della Trombosi come consigliere (1992-1994 e 2012-2014), segretario (1996-2004), vicepresidente (2004-2006), presidente (2006-2008) e past-president (2008-2010). E' stato consigliere (1994-2006) e segretario (2003-2006) della Federazione dei Centri per la Sorveglianza dei pazienti Anticoagulati. E' membro del gruppo di studio ISO (ex SPREAD) per le linee guida italiane per l'ictus cerebrale e del gruppo di studio Trombosi della Società europea di cardiologia (ESC) e della Società Italiana di Cardiologia (SIC) ed è stato Consigliere della sezione tosco umbra della Società Italiana di Medicina Interna. E' stato Chairman dell'Operative group della rivista Internal and Emergency Medicine (2006-2009) e poi Editor-in-chief dal 2009 a tutt'oggi.



Corinna Raimondo - Northwestern University, Chicago (USA)

Senior Compliance Specialist for the Office for Research Integrity and Instructor of the Responsible Conduct of Research training at Northwestern University (USA). Corinna holds a PhD in Physical Chemistry from the Institut de Science et d'Ingenierie Supramoleculaire of Strasbourg University (France), a Master of Law from Northwestern University (USA) and a Master of Science from the University of Genoa (Italy). In her current role, she facilitates research misconduct proceedings at Northwestern and she teaches best research practices to grad students and postdocs in the McCormick School of Engineering. She is active at the federal level, both from a teaching perspective as well as from a research misconduct one.





Emanuela Rasini - University of Insubria, Varese (I)

Emanuela Rasini is a technician at the Center of research in Medical Pharmacology, she holds a degree in Biological Sciences (University of Pavia, Italy, 1995), and a specialization in Pharmacology (University of Pavia, Italy, 2000). She is responsible for the flow cytometry service of the Center of Research in Medical Pharmacology and has been working in flow cytometry for more 15 years, developing and validating a number of original assays and procedures that have been used in immunopharmacological studies with particular regard to the mechanisms regulating spontaneous and acquired immune response in health and disease. Her principal research interest is in the field of the "neuroimmune pharmacology", with particular regard to the molecular mechanisms and the clinical relevance of the catecholaminergic modulation of immune response.



Laura Ribeiro - University of Porto (P)

Laura Ribeiro is Professor of Biochemistry at the Faculty of Medicine of the University of Porto since 1999 and more recently also of Humanities in Medicine. She holds a PhD in Human Biology. She coordinates the Master course in "Academic and Clinical Education" involving 7 faculties of the UP. She has the regency of the mandatory curricular unit (CU) "Integrated Master Thesis Project" and the optional CU "Academic integrity" of the master degree in medicine and she is responsible for teaching several units of PhD and master courses held at FMUP. Researcher at Instituto de Investigação e Inovação em Saúde (I3S), University of Porto, she was the Principal Investigator of the Project "RES4MED: learning medicine through research (EXPL/IVC-PEC/1302/2013) on the research area "Institutions, Values, Beliefs and Behavior-Education and Science Policy", supported by Foundation for Science and Technology. She coordinates the Program "Academic Mentoring" since 2013 and presently is member of the ENAI - European Network for Academic Integrity. She is presently the Director of the International Relations and Mobility Office of FMUP.



Silvia Scalzini - LUISS Guido Carli University, Rome (I)

Silvia Scalzini is Postdoctoral Researcher at LUISS Guido Carli University, Rome. Her current research interest focus on Italian, International and European Intellectual Property Law, Competition Law, Data Protection Law and Research Ethics. Silvia holds a PhD in Individual Person and Legal Protections (cv European Law and New Technologies) from Sant'Anna School of Advanced Studies (2016), a Law Degree (Laurea Magistrale in Giurisprudenza) from University of Pisa (2011) and a Graduate Diploma in Law from Sant' Anna School of Advanced Studies, Pisa (2013). She was also scholarship holder at the Max Planck Institute for Innovation and Competition, München (2014-2015) and visiting scholar at École Normale Supérieure de Paris (2009) and at Institute Suisse de Droit Comparé, Lausanne (2014). Silvia has served, as expert ad acta, in the Research Ethics and Bioethics Advisory Commission of the National Research Council of Italy (CNR), where she currently coordinates the scientific secretariat of the working group on Big Data. She is Fellow of the Italian Academy of the Internet Code, Chief editorial staff member of "Opinio Juris in Comparatione. Studies in Comparative and National Law" and Secretary at the Disiano Preite Association. She is Avvocato and member of the Italian Bar.



Alessandro Squizzato - University of Insubria, Varese (I)

Alessandro Squizzato, MD PhD, is Associate Professor of Internal Medicine at the University of Insubria, Varese, Italy. Founder and member of the 'Research Center on Thromboembolic Disorders and Antithrombotic Therapies', University of Insubria, Varese, Italy, of the TRIP (Thrombosis Research Italian Partnership), and of the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation)-Dispute Working Group. Author of more than 180 scientific paper. More info at *https://www.uninsubria.it/docenti/alessandro.squizzato



Loreta Tauginienė - Mykolas Romeris University, Vilnius University (LT)

Associate Professor and Head of Academic Ethics Centre at Mykolas Romeris University; Researcher at Vilnius University. Her research ranges from integrity management, academic/research ethics/integrity, and social responsibility until public engagement and citizen science. She has published ca. 20 publications, including in collaboration with Fraunhofer Institute for Systems and Innovation Research ISI (Germany) about responsible research and innovation, Edward Elgar Publishing about the grounded theory for corporate social responsibility research and Routledge about public participation; forthcoming book chapter on university social responsibility in collaboration with Emerald Publishing. Recently she is enrolled in the COST Action CA15212 (https://www.cs-eu.net/) related to scientific literacy and innovation where she has a role of co-chair of the work group "Enhance the role of Citizen Science for Civil Society" as well as the leader of a work package in the project "European Network for Academic Integrity". She is member of the Editorial Boards in the Journal of Management and Change and Journal of Academic Ethics, Board member of the European Network for Academic Integrity (ENAI as association) as well as a Chair of Interim Working Group on Academic Integrity and Ethics under Lithuanian University Rectors' Conference.



Who should attend this School?

Biomedical research is among the main keys to **progress** and **well being** in modern societies, and **the profession of biomedical researcher** is among the most **intellectually exciting**.

Nonetheless, in the last decades pursuing a career as researcher in biomedicine has become more and more difficult, mainly due to **increased competition** and **decreased funding**. Pressure of severe competition for funds and to obtain and secure a staff position in academic institutions are among the major factors leading researchers to breach their professional integrity by adopting **questionable research practices** and ultimately committing **scientific misconduct**.

According to ENAI, "academic integrity" means "compliance with ethical and professional principles, standards and practices by individuals or institutions in education, research and scholarship." (1). Research integrity may be defined as active adherence to the ethical principles (honesty, trustworthiness, and high regard for the scientific record) and professional standards essential for the responsible practice of research (2).

Scientific misconduct results in **harm to individuals and society**, e.g. due to the development of ineffective and/or unsafe drugs or other therapeutics or just wasting money and resources in misconducted research activities, **direct damage to science itself**, by creating false leads for other scientists to follow, and/or forcing others to waste time, effort and money to reproduce fraudulent results, **degradation of relations among scientists**, between senior researchers and students, and between researchers and agency programme managers, damage to science through the **undermining of the public's trust in science** (3).

Lack of knowledge/preparation about the realities and stresses of a scientific career as well as lack of awareness of the rules and standards of proper scientific conduct are among the main factors leading young researchers to scientific misconduct and career failure (3).

The INSUBRIA SCHOOL ON METHODOLOGY, ETHICS AND INTEGRITY IN BIOMEDICAL RESEARCH aims at addressing the unmet needs of young scientists by providing a comprehensive knowledge of the fundamental principles, methodologies and practices of preclinical and clinical research.







The School, now in its second edition, is organized into five modules each including cutting-edge lectures given by internationally acknowledged experts in their respective fields. One module focusses specifically on **preclinical research and laboratory animal care and use**, while another one deals with **human subject research and institutional review boards**. Two modules are dedicated to **writing and understanding biomedical research papers** and to the **publication process**, including the editorial management of manuscripts, the peer review process as well as the fundamentals of citation analysis and bibliometrics. A module dedicated to **research integrity**, scientific misconduct and how to prevent and deal with it at the individual as well as at the institutional level, sets the frame of the School ultimately aiming at promoting responsible research practices.

The format of the School provides an intense one week of full immersion, fostering the direct contact of young researchers with the experts who provide lectures, with the ultimate goal to foster an effective transfer of knowledge and information, not limited to the 40 hours of lectures and formal training.

As a whole, the School is thus addressed to both young researchers planning to pursue their career into science and research as well as to those who would like to benefit from a thorough knowledge of the principles and methodologies underlying high quality research. This School is also part of a generalized effort aimed at training "Physician-scientists", defined as those with MD degrees who devote a substantial part of their professional effort to biomedical research, ranging from basic science, through translational and patient-oriented research, to advance medical sciences from the bench to the bedside and maintain rigorously high academic standards in basic and clinical research.



References

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- 2. Korenman SG. Teaching the Responsible Conduct of Research in Humans (RCRH). © 2006 University of California Regents.
- 3. OECD consensus report. Best Practices for Ensuring Scientific Integrity and Preventing Misconduct. 2007



COURSE VENUE

Collegio Universitario di Varese maps.google.com - http://goo.gl/Z70Ell





$For \ additional \ information, please \ contact \ the \ Organizing \ Secretariat$

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Via Ottorino Rossi n. 9, 21100 Varese VA, Italy
Phone: +39 0332 217401-397401 - Fax: +39 0332 217409-397409
E-mail Research_Integrity@uninsubria.it

HOTELS CLOSE TO THE COURSE VENUE

Yes Hotel

Via Fusinato, 35 21100 – Varese – ITALY Phone (+39) 0332 1570325 Fax (+39) 0332 1562897

- E-mail reservation@yeshotel.it
- Website www.yeshotel.it Single Room - € 55,00

Double Room (one person) - € 60,00

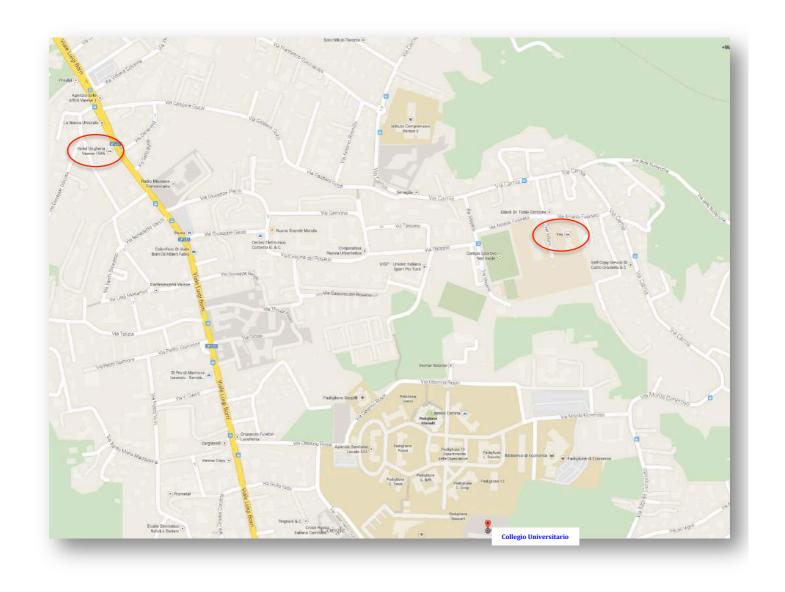
Double Room - € 70,00 Triple Room - € 110,00

Hotel Ungheria

Viale Luigi Borri, 98 21100 - Varese - ITALY Phone (+39) 0332 264325 Fax (+39) 0332 264256

- E-mail info@hotelungheria.it
- Website www.hotelungheria.it Single Room - € 64,00

Double room (one person) - € 73,00





REGISTRATION & FEES

A maximum of 50 participants will be admitted to the School. Admissions will be on a first-come-first-served basis, with priority given to PhD students and Medical Doctors attending a school of specialization. To register, please use the **Registration Form** on page 8.

Upon confirmation of admission, participants will be asked to pay a fee of € 5,00, including insurance for liability and against accidents (assicurazione per responsabilità civile e contro gli infortuni).

No fee will be asked to participants already enrolled in a PhD program and/or in a school of specialization at the University of Insubria.

Registration entitles to attend all the modules of the School and includes: School kit, coffee breaks and lunches.

Registration fee can be paid by bank transfer to:

Dipartimento di Medicina e Chirurgia Banca Popolare di Sondrio, Succursale di Varese Viale Belforte n. 151, 21100 Varese

IBAN: IT16 D 05696 10801 000085102X91

COD. SWIFT/BIC: POSOIT22

Reason for payment/transfer: "Contributo di iscrizione alla SECOND INSUBRIA INTERNATIONAL SCHOOL IN METHODOLOGY, ETHICS AND INTEGRITY IN BIOMEDICAL RESEARCH".

Certificate of attendance and CFU/ECTS

A **certificate of attendance** will be given to all participants attending at least 80% of the School.

Travel & accommodation grants

A limited number of **travel & accommodation grants** will be available to eligible participants.

Eligibility criteria are:

- (i) less than 35-year old;
- (ii) non-tenured;
- (iii) submission of a motivated letter of application together with the registration form.

The grant will consist of a contribution of up to 125,00 Euro (up to 250,00 Euro for participants coming from outside of Italy). Travel refund will be assigned upon presentation of tickets and bills.

A limited number of places are available free of charge at the local University College. Interested applicants should tick the option on the registration form.







Registration Form

Please type CLEARLY in BLOCK LETTERS or PRINT

□ PhD Stude	nt	University of			
		PhD program in	(letter of PhD program Coordinator attached)		
☐ Medical Do	octor in specialization	University of			
	•	School in			
_			(letter of School Director attached)		
□ Other		Institution			
		Position			
Gender	F □ M Family Na	ame	First Name		
Street			No		
ZIP Code	Town		Country		
Tel	Fax	E-ma	il		
I would like t	o apply for:				
	ccommodation grant	☐ I'm <35-year old ☐ I'm non-tenured ☐ letter of motivat			
□ accommod	ation at the University (
Deadlines:	14 th September 2018 5 th October 2018		or Travel/Accommodation		
INSUBRIA INT	Or	ganizing Secretariat	ne latest by 5 th October 2018 to: of the CS AND INTEGRITY IN BIOMEDICAL RESEARCH		
	Center of Research in I		gy, University of Insubria,		
	Tel.: +39 03	32 217401 - Fax: +3	•		
Data	Ci	naturo			
Date	Signature				



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SECOND INSUBRIA INTERNATIONAL SCHOOL on METHODOLOGY, ETHICS and INTEGRITY in BIOMEDICAL RESEARCH

Promoting responsible conduct of biomedical research

12th-16th November 2018 University of Insubria



In collaboration with

PhD Course in Clinical and Experimental Medicine and Medical Humanities
School of Specialization in Medical Pharmacology
Centro Ricerche sulle Malattie Tromboemboliche e sulle Terapie Antitrombotiche
Centro Thomas C. Chalmers e Alessandro Liberati"
centro di ricerche interuniversitario sulla metodologia delle revisioni sistematiche
e la promozione della "evidence-based medicine"

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