

European Fellowship in Research Ethics

'from capacity-building to capacity-sharing'

10 June to 5 July 2019

Contact: fpc@gcpalliance.org



Handbook

(10 April 2019, Version 3.0)

Welcome

The European Fellowship in Research Ethics is designed to train members and administrators of ethics committees from countries coming from outside Europe as well as those within Europe. The programme has been designed by the Good Clinical Practice Alliance – Europe (GCPA) and the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) in discussion with interested institutions in Europe, Asia, and Africa.



From June 10th to July 5th, 2019, the European Fellowship in Research Ethics will expose members of ethics committees, ethics committee administrators, and researchers in the health sciences to research ethics practices, ethical review procedures, and regulatory science in Europe. This is a pilot project aimed at developing a 'European Ethics Committee and Regulatory Fellowship Programme for Clinical Trials' (EECRF).



The Fellowship Programme is based in the historic university town of Leuven and takes the Fellows on a journey through research ethics, ethical review, and regulatory science in Belgium, The Netherlands, and the United Kingdom. The Fellows have the opportunity to visit leading research and regulatory institutions, and thus learn first-hand European practices alongside European ethics and research guidelines & regulations.

The programme provides a comprehensive and in-depth examination of European research ethics, ethical review practices, and regulatory science at the European Union level and at the Member State level. The programme also allows for the fellows to share their experiences with the institutions they visit as well as among themselves.

Fellowship Goals

The primary objective of the European Fellowship in Research Ethics is to train well qualified scientists, ethicists, administrators, regulators, and teachers in European ethics and regulation for health research, including clinical trials, epidemiology, population science, social science, and behavioural science.



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The Fellows learn from one another as well as from the faculty, and they share their knowledge and experience. The aim is to build cross-cultural understanding and professional friendships that create a reliable scientific and ethical foundation for the exchange of research and the promotion of health. Fellows are expected to return to their home countries and institutions with a new awareness of how to promote ethics and ethical review in health research that will lead to the strengthening of their institutional and national systems.

The Fellowship also promotes cultural goals, including the sharing of knowledge as well as sharing history, law, politics, and societal values. The Fellows learn “This is how we do things in Europe.” and they share with those in Europe “This is how we do things in my home country.” They are taken inside the heart of Europe, but without the suggestion that this way of doing things is best, this way of life is best. Indeed, it is the exchange of models and understanding that is valued.



Participant Profiles

The total number of trainees is at least 8 but no more than 20. The participants that will most benefit from the Fellowship Training are

- members of Ethics Committees / Institutional Review Boards (ECs/IRBs), including members of national research ethics committees, who wish to augment their expertise while also improving the quality and capacity of their home EC/IRB;
- administrators of ECs/IRBs who want to improve the workflow and functioning of their home EC/IRB;
- members of scientific review boards for research proposals;
- research administrators who want to improve the quality of the research in their institutions and create links with European institutions; and
- professionals with a need to improve their understanding of research ethics and regulatory affairs in Europe.

Participant Requirements



The participants are required to complete an application form and have a letter of approval from their home institution. There are a limited number of places and participants will be selected based on their background, interests, and what they plan to do following the fellowship.

Participants are required to have a Schengen visa that is valid for the entire period of the programme. Your passport will likely need to be valid for 6 months beyond your stay. The Fellows will also travel to the

United Kingdom and you may be required to have a visa for the United Kingdom, depending upon the country from which you are coming.



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Participant Attendance



The participants are expected to attend all sessions of the Fellowship training and actively participate. They are to be on time and have done the preparatory readings and question formulations. The use of e-mail, social media, phone calls, and portable devices not related to the session is strongly discouraged. Fellows are not permitted to travel except on those days indicated as 'Free' in the Fellowship Curriculum. [This walking map](#) shows you how to arrive at the classroom from the

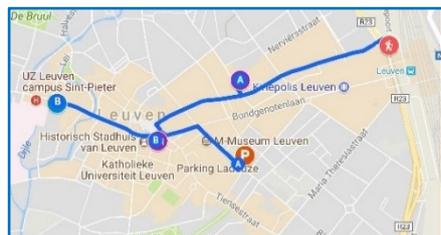
Ambassador Suites, The Fourth Hotel, Parking Ladeuze, and Leuven's Central Train Station and Bus Terminal.

The sessions may be photographed, videotaped, or voice recorded by Faculty members of the Fellows. These recordings may be used further privately or publicly. By attending the Fellowship Programme, you agree to participating in these recordings.

Participants must arrive on or before Sunday, 9 June 2019 in Belgium and remain until Saturday, 6 July 2019.

Classroom Locations

The principle venue for the Fellowship is in the Augustinessenklooster (The Cloister of the Augustinian Sisters) Romaanse Poort (Roman Gate) on the Brusselsestraat 63, 3000 Leuven, Belgium. (See this [map of places in Leuven](#).) This is an historic building and the site of the oldest hospital in Leuven dating back to the 11th Century AD. Classes and workshops are held in Room A06 on the ground floor (with some possible exceptions). As indicated in the curriculum, classes and workshops will also be held



at the Global Health Institute, University of Antwerp; The European Commission in Brussels; the European & Developing Countries Clinical Trials Partnership (EDCTP) office in The Hague, the Dutch Central Ethics Review Committee (CCMO) in The Hague, and the Medicines Evaluations Board (CBG) in Utrecht.

Participation in Learning

The Fellowship Mentor and Faculty are responsible for the teaching. The Fellows are responsible for the learning, collectively and individually. The first half hour of each day (except for the first day) will be dedicated to reviewing what was learned the previous day and preparing for the day's agenda. The last hour of each day (except for the last day) the day's learning will be reviewed and evaluated, and the next day's learning prepared. A different fellow will be assigned for each morning and for each evening session. A fellow will also be assigned to lead each of the workshops and guest lectures.



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The European Fellowship's Virtual Classroom and Work to be Completed in Advance

A virtual classroom has been created using Google Classroom. This allows the Fellows and Faculty to communicate with one another more easily as well to organise documents and presentations. The virtual classroom also allows you to share and receive real time updates and share messages in an easy and intuitive environment. Each section of the course has been provided as an 'assignment' where the Faculty can upload their presentations and documents, and the Fellows can select what they are interested in to read. Faculty can also provide instructions on their section directly to the Fellows.

If you do not have a Google Account (gmail), you will need to make one. All of the Fellows and Faculty are asked to have one and participate in the Google Classroom. The virtual classroom provides a guided framework of references and allows the Fellows to learn on their own, even choose what they read or do not read.

Participant Housing

The Fellowship Programme recommends housing with Ambassador Suites Leuven, Condo Gardens Leuven, and Budget Flats Leuven. These are all operated by the same company and can be found on the website <https://www.be-housing.be/en/aparthotels-leuven> This [map of places in Leuven](#) shows you where the recommended housing is located in relation to the classroom and other activities in Leuven. We will also provide you information about booking hotels in The Netherlands and London. You will be responsible to make the booking yourself.

Belgium and The Netherlands

The Fellows will be will largely be housed in Leuven, Belgium. On this [map of places in Belgium and The Netherlands](#) you can see the different places we will visit, in Leuven and in Belgium and The Netherlands.



Belgium is located in 'the heart of Europe'. It is rich with history going back to the Roman period and was at the crossroads of the Medieval Period, the Renaissance, the Scientific (and Medical) Revolution, the French Revolution, and World War I & II. It has many historically famous cities, including Leuven, Brussels, Antwerp, Ghent, Brugge, Dinant, Liège.



Belgian has three official languages: Flemish (Dutch) spoken in the north, French spoke in the south, and German spoken by a small group in the East on the German border. The Fellows will spend their time in the Dutch-speaking area (Leuven and Antwerp) and in Brussels (bilingual).

The language of instruction and discussion will be English. All of your faculty speak excellent English. And indeed, in both Belgium and The Netherlands you will likely not encounter anyone who does not speak

English quite well.



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Brussels is considered to be the Capitol of Europe, housing the European Parliament, The European Council, the European Commission, and other European instances.

Leuven is geographically small. Everything is within easy walking distance. Leuven is famous for being home to both the oldest Catholic university in the world (1425) and the largest beer brewing company in the world (AB InBev). Leuven is also full of shops, restaurants, cafes, and beautiful squares.

The Netherlands shares a great deal of history with Belgium as well as the language, Dutch. It has many beautiful cities that are popular with Tourists, including Amsterdam, Gouda, the Keukenhof (tulip) Gardens, Delft, Leiden, Maastricht.

Paris, London, Amsterdam, and Cologne are all within 3 to 4 hours by high speed train (Thalys, Eurostar) from Leuven (via Brussels South).



Participant Leisure & Sports

There are a wide variety of leisure and sport opportunities in Leuven. Several sightseeing places as well as parks are indicated on this [map of places in Leuven](#). Brussels, Ghent, Bruges, the seaside, and other places in Belgium are just a relatively short train ride away and good for a day's outing. Paris, Amsterdam, and places in Germany can be visited on the 4-day weekend, Thursday to Sunday, 10 to 13 May.



If you are interested to walk or run then the Leuven Sports Center, the Park Abbey, and the Provencial Domain of Leuven (Kessel-Lo) are good choices. If you want to swim; play tennis or squash or badminton; play basketball; cycle; football, or just about any sport, simply let us know and we can arrange it for you.

Food & Dining

There are no meals provided by the organisers. Fellows need to provide all their own meals. Belgians traditionally eat meat, potatoes, and vegetables at their main meal. The cooking is similar to French cooking. However, in Leuven you can find food from all over the world, including rather good supermarkets for Asian, African, and Middle East food as well as many diverse restaurants. This [food shopping map](#) shows some places to shop for food as well as a Thai restaurant and an Ethiopian restaurant.



Breakfast and dinner, you will have to arrange on your own.

We will have lunch every class day from 12:30 noon to 1:30 pm. When we are in Leuven, we have a small room in the Roman Gate building reserved for our lunch. However, only water, coffee, and tea will be available. You will need to bring your own sandwiches or something



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you prefer with you. There are also restaurants and shops in the area. Just be careful because one hour is rather a short amount of time.

If you have any dietary requirements or food allergies, please let us know as soon as possible, preferably before you arrive.

Participant Expenses

The total expense for a Fellow coming from outside Europe is estimated to be between 4000 and 5000 Euros, plus the 1500 tuition fee.

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| Tuition Fee | 1500 Euros |
| Per diem (suggested) | 50 Euros per day = 1250 Euros |
| Housing in Leuven (21 days) | Executive rooms (single occupancy): 1300 Euros Normal room (double occupancy): 600 Euros All rooms are equipped with a kitchen. [options are available if rooms are booked early on] |
| 4 Nights Hotel in The Netherlands | Approximately 400 Euros |
| 2 Nights Hotel in London | Approximately 250 Euros |
| Airfare | Approximately 1500 Euros |
| Local Transportation and Cultural Programme | A single fee of 600 Euros covers all transportation expenses, including buses and trains as well as all museum tickets and guides. This fee can be paid in cash upon arrival. 600 Euros may also be paid by bank transfer to the Good Clinical Practice Alliance – Europe (GCPA) bank account (account # 652-8049542-79; Record Bank, Wilsonplein 5, bus i, 9000 Gent, Belgium [IBAN BE58652804954279]). Please indicate your name and that this is for EFRE Transportation and Cultural Programme. |
| Insurance (required) | 108 Euros |

Please note that changing money in Belgium is very difficult due to money laundering laws. There are a few currency exchange places at the airport in Brussels (Zaventem).

The Fellows are required to book their own transportation to and from Europe as well as their own lodging and to cover all their expenses. No meals are provided. There are no scholarships or financial assistance of any kind available beyond the waiver of tuition.



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The Weather

During the month of June, you may expect every day to be rainy and wet with temperatures between 12 and 25 degrees. You may also expect every day to be sunny and warm with temperatures between 25 and 30 degrees. And everything in between you may expect as well, including some surprises.

Fellows are strongly advised to bring comfortable shoes for walking. Throughout Leuven and in all of the places visited by the Fellowship, there are many cobblestoned streets which are challenging for walking.



Arriving in Leuven

The easiest way to travel to Leuven from the Brussels Airport is by train. When you come out of customs into the arrival hall, turn right and take the escalator or elevator down to the train station in the airport. Take the train that goes directly to Leuven. It is about a 20-minute trip. The cost is 9.40 Euros one way. There are 2 to 4 trains per hour. Most of you will arrive on a weekend or during a holiday so there will only be 2 trains per hour. This is the same when you return from Leuven to the airport after the Fellowship is completed. You need to purchase your ticket before boarding the train. Leuven will be the first stop of the train. A taxi from the airport to Leuven will cost you 80 to 90 Euros one way. If there is any traffic, the taxi will be slower.

When you arrive at the train station in Leuven, you can either walk or take a bus or take a taxi to your lodgings or to the classroom. From the train station in Leuven to the center of Leuven (the City Hall), it is a one kilometre walk down the Bondgenotenlaan. From the center of Leuven every other place in the city is within a one-kilometer walk. There are also buses and taxis available.

There will be no one to meet you at the airport when you arrive in Leuven. This is also the case at the end of the Fellowship when you leave. You will be fine. It is easy. Everyone speaks English as well. If you have any problems, you can always call Francis on his mobile phone.

Medical Insurance

You are responsible for your own medical expenses during the course of the programme. You are therefore required to have valid medical insurance that will cover any medical expenses you may encounter during the programme. If you cannot have medical insurance from your home institution or home country, we can apply to have it provided for you in Belgium. Please contact us for this information.

Identification

In Belgium and The Netherlands, you are legally required to carry official identification with you at all times, either your European identity card or your passport. In order for you to enter official government offices, you need to show your passport or European identity card.



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Evaluation

The Fellowship programme is designed for continual quality improvement as well as the participation of an independent evaluator and an overall evaluation by the participants. The Fellows will be evaluated based on their participation, report writing, final paper, and the passing of a final evaluation. Successful Fellows will receive a Certificate of Completion.