REQUEST FOR ETHICAL ADVICE / DEMANDE D’AVIS ETHIQUE

INFORMATION

To read before filling in your application: The mission of the Faculty Advisory Ethics Committee is to provide an enlightened opinion about studies involving human beings, conducted in the framework of the activities of the Faculty of Psychological Sciences and Education at the Université Libre de Bruxelles (ULB), and in specific circumstances by other Faculties or Institutions at ULB. We are working in close collaboration with the Erasme-ULB Hospital-Faculty Ethics Committee (homologation 021/406), who in some cases (see below, Class 2 studies) will issue an ethics clearance for your project based on the informed opinion of our Faculty Advisory Ethics Committee.

Your request can correspond to one out of the three following categories, with a different processing:

Class 1: studies with a clear medical or invasive dimension, for example (non-exhaustive list) a diagnostic or revalidation intervention in hospitalized patients or in patients enrolled via a hospital-dependent recruitment line, psychopharmacological manipulations, administration of experimental medical treatments, products or substances, collection of biological material or use of biological material originally obtained for medical purposes or from previous research or from other researchers. For these Class 1 studies, the Faculty Advisory Ethics Committee is not qualified, and you must submit your request directly to the Erasme-ULB Hospital-Faculty Ethics Committee (www.erasme.ulb.ac.be/fr/ethique). Generally speaking, if your study is conducted in the hospital or in a related institution, and/or a proactive recruitment process is conducted in the framework of a medical setting, and especially if the patient must be registered to the "Guichet Unique" of the Biomedical Research Department (SRB\(^1\)), then this is a Class 1 request. The Erasme-ULB Hospital-Faculty Ethics Committee will also directly handle ethical advices related to research projects involving healthy subjects in infrastructures located at the hospital, for example (non-exhaustive list) structural or functional Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), Magnetoencephalography (MEG), and Transthoracic Magnetic Stimulation (STM) studies, or studies that require a specific medical supervision. Finally, please note that if your study is conducted in another hospital than Erasmus-ULB (for example, CHU Brugmann or Saint-Luc), they may have their own ethics committee, where you need to submit directly an application to conduct your study.

Class 2: studies in the field of experimentation on human beings, aimed at the development of our knowledge in psychological sciences and education (mental, emotional, cognitive processes, personality, learning processes ...). In this case, the Erasme-ULB Hospital-Faculty Ethics Committee will validate the decisions of the Faculty Advisory Ethics Committee. Class 2 studies may involve non-invasive measurements of physiological or neurophysiological activity without diagnosis value\(^2\), usually in healthy participants, for example (non-restrictive list) electroencephalogram (EEG; evoked potentials or continuous), electromyogram (EMG),

\(^1\) www.erasme.ulb.ac.be/fr/enseignement-recherche/recherche-biomedicale/soumission-d-un-nouveau-projet-de-recherche-clinique

\(^2\) Except from the Faculty ethics advice 026/2011: Studies measuring physiological or neurophysiological activity can be conducted within the Faculty after approval by the ethics committee, provided that these studies meet at least these conditions:

(a) the equipment is used according to the state of the art, by trained researchers
(b) the study is conducted for the purpose of experimental research
(c) participants receive complete information and sign an informed consent document in which it is explicitly specified that no diagnosis and / or clinical interpretation can be derived from the collected data
electrocardiogram (ECG), transcranial direct (tDCS) or alternative (tACS) current stimulation, and optical imaging (Near Infrared Spectroscopy; NIRS). Recordings are conducted in dedicated rooms at the Faculty, or in ambulatory conditions (for example, polysomnography [PSG] at home, or actimetry). Clinical populations (for example, patients with a chronic condition or people with a disability, children with learning disorders, individuals potentially or actually experiencing psychological suffering, etc.) may also be included in the Class 2 category, depending on the modality of the recruitment, the experimenters' qualification and the location where the study takes place. Generally speaking, if you are recruiting by way of global broadcast (for example, flyers, ads in social media or thematic groups), and participants spontaneously manifest themselves to enrol in the study (that is, they are not specifically and personally invited to participate in the context of a medical consultation, for example), then they do not necessarily need to be registered at the "Guichet Unique" (see above in Class 1). Studies for which a risk assessment for the participant is necessary (for example, risks of a breach of privacy, possible psychological consequences and necessary precautions, so-called fragile populations or persons with reduced protection levels, ...) also fall into the Class 2 category. In summary for Class 2 studies dealing with research projects falling into the domains of expertise of our Faculty, the Faculty Advisory Ethics Committee will assess itself the ethical requests, and then provide a short motivated advice to the Erasme-ULB Hospital-Faculty Ethics Committee, who will validate it and provide an official clearance in its capacity as homologated ethics committee.

Class 3: Fundamental studies in the fields of psychological sciences and education that do not qualify for the above Class 1 or Class 2 categories. Class 3 studies do not require the ethical clearance of an homologated ethics committee. In this context, the Faculty Advisory Ethics Committee will assess itself the ethical requests and issue an advice (not legally binding). Among other possibilities (non-exhaustive list), Class 3 includes ethical advices related to surveys (insofar as they do not involve the collection of sensitive personal medical data), behavioural studies in healthy participants with performance measures (for example, language, memory, attention ...), administration of questionnaires or scales about personality traits or attitudinal orientations, dynamics of social interactions, implementation of experimental didactic protocols, well being development and support programs, etc.

Whatever the Class of your request, we remind you that as of September 1, 2016, all experiments on human beings must be covered by a specific insurance, which can be obtained (amongst other possibilities) at the legal department of the ULB (see procedure in annex).

If in doubt about the category of your study, you can contact a member of the committee or write to Ethique.Psychologie@ulb.ac.be.