CENTRO INTERUNIVERSITARIO DI FLEBOLINFOLOGIA (CIFL)
INTERUNIVERSITY CENTER OF PHLEBOLYMPHOLOGY
International Research and Educational Program in
Clinical and Experimental Biotechnology

INSTITUTIONAL REVIEW BOARD - INDEPENDENT ETHICS COMMITTEE
IRB-IEC
REGULATIONS

Art. 1 Institution

The INTERUNIVERSITY CENTER OF PHLEBOLYMPHOLOGY (CIFL) International Research and Educational Program in Clinical and Experimental Biotechnology affirms its policy to safeguard and respect the rights and welfare of human subjects in scientific research. In order to carry out this obligation, the institution, through its Institutional Review Board – Independent Ethics Commitee (IRB/IEC), is responsible for conducting initial and continuing review of all research that involves human subjects. Therefore the Center requires prior review and approval for all research involving human participants and provides for an IRB-IEC to carry out this review and approval process.

The IRB/IEC will proceed only to evaluation of Background and aims, matherial and methods, economic sustainability and overall validity of the research project.

Once approved the evaluated project will be subject to the Official Local Ethic Commitee for final approvation and application of the study protocoll, whereas mandatory.

The Center accepts the responsibility to meet the compositional requirements of IRB/IEC membership, and to provide both meeting space and sufficient staff to insure the IRB/IEC’s timely and appropriate review and record keeping duties.
The IRB/IEC of CIFL is subject to local rules and laws in force (Decree of the Italian Ministry of Health 12/05/2006)

**Art. 2 Composition**

IRB/IEC of CIFL is deliberated by Executive Committee of CIFL and must:

- Consist of at least five members with at least one member coming from each University of CIFL.
- Include at least one scientist member;
- Include at least one non-scientist member
- Include at least one member who is not otherwise affiliated with CIFL and who is not part of the immediate family of a person who is affiliated with CIFL
- Be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote complete and adequate review of research activities commonly conducted by individuals at CIFL;
- Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice;

When reviewing research involving a vulnerable population, such as children, prisoners, pregnant women or handicapped or mentally disabled persons, the IRB includes one or more members who are knowledgeable about and experienced in working with these subjects (Consultants). In fact, either before or during review of a protocol, the IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that routinely available on the IRB. Consultants may be asked to provide their expertise regarding a specific issue, or provide general comments regarding a project. Consultants are asked to provide comments in writing, and may be asked to attend a convened IRB meeting but will be excused prior to the vote.

A consultant may not vote or count towards quorum. Written consultant comments are retained in the protocol files.

IRB Chair corresponds to the Director of CIFL. Vice Chair and Secretary are appointed by the Executive Committee of CIFL.

Each IRB serves a one-year term of service. Each member may be confirmed or replaced by Board of Directors of CIFL.

**Art. 3 Scope of Activities**

The IRB reviews applications at three levels. Researchers have the initial responsibility to determine the level of review of their project; however the IRB has the ultimate responsibility to identify this level for committee review. These levels are briefly introduced below
**Level 1: Review for Exempt Status**
Research is reviewed for exempt status by an IRB committee member if it involves minimal or no risk procedures such as surveys/interviews, observation of non-institutionalized adults, and educational tests. *Exempt from Committee review does not mean exempt from consent!* Exempt research is exempt only from full Committee review. Any research involving protected classes or vulnerable populations of subjects (such as children, prisoners, pregnant women, mentally disabled persons, research by faculty on college students enrolled in their own courses, or economically or educationally disadvantaged persons) including surveys, is never exempt.

**Level 2: Expedited Review.**
Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Requests that qualify for this level of review require reading by the Chair, the Vice Chair and the Secretary. The reviewers may exercise all the authorities of the IRB except disapproval. If the application is recommended for disapproval, the full committee must review it. Only the full IRB can disapprove an application. Research at the Expedited level covers minimal risk procedures such as those involving small amounts of blood, dental plaque, moderate exercise, voice recordings, case-control study etc.

**Level 3: Full Review.**
All research not falling into the other two categories and most research involving children or minors or randomized controlled trial of a new drug requires full review because it places the subject at more risk than research that qualifies for exempt or expedited review. Research requiring full review means that it is read, discussed, and voted upon by the full IRB committee. Full Review will be forwarded to Ethics Committee of one University of CIFL for final approval.

**Art. 4 - Decisions**
IRB decisions and requirements for modifications will be conveyed promptly to investigators in writing by e-mail. Written notification of decisions to disapprove an application will be accompanied by reasons for the decision with provision of the opportunity to respond.

The IRB will have the authority to suspend or terminate previously approved research when it determines that the research is not being conducted in accordance with the stipulations made by the IRB, or if the approved project experiences unexpected serious harm to subjects.

Researchers who propose to undertake research involving human subjects acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects. They also must comply with all applicable provisions outlined in this document. Research investigators involving human subjects also shall be responsible for complying with all IRB decisions, conditions, and requirements. Investigators will promptly report to the IRB anticipated changes they may propose or that may be imposed by an external IRB for previously approved human subject research activities. Researchers will not initiate any changes without IRB review and approval except where necessary to eliminate apparent immediate hazard to subjects. Researchers will report promptly to the IRB any injuries or unanticipated problems involving risk to research subjects or others.
Art. 5 Initial IRB Review process

Initial review application materials must be submitted using the electronic IRB Protocol Management system of CIFL, and include information in sufficient detail in order for the IRB to make the determinations required.

The application should include the below-listed items. The IRB retains final authority to require additional information (even for exempt protocols), or determine that sufficient information is included in the original submitted application that excludes one or more of the below-listed items.

Application Materials:

a) Research Protocol or Existing Data Research Protocol

b) Proposed informed consent document (unless consent is to be waived by the IRB or the project is deemed exempt)

c) Additional study documents related to human subjects including data collection instruments and recruitment materials

d) Any relevant grant application(s)-

e) Bio-sketch or CV for all investigators