Organization Rules
of the **Center for Evidence Based Oncology (CEBO)**
of the Institute of Biostatistics and Analyses,
Faculty of Medicine and Faculty of Science, Masaryk University

Article 1
Introductory provisions

1. CEBO is a valid abbreviation of the Center for Evidence Based Oncology of the Institute of Biostatistics and Analyses, Faculty of Medicine and Faculty of Science, Masaryk University.

2. CEBO has been established as an independent section of the Institute of Biostatistics and Analyses, Faculty of Medicine and Faculty of Science, Masaryk University (hereinafter referred to as "IBA"). CEBO and its staffing are appointed by the director of IBA; CEBO establishment, management and operation conform to the organization rules of IBA, regulations in force of the Masaryk University and Czech legislation in force.

3. CEBO activities are controlled by the Programme Council, which informs regularly the Scientific Council about its activities, in compliance with this organization rules.

4. The main reason for establishing CEBO has been the current unsatisfactory situation in the area of clinical trials projects which would be initiated, performed and evaluated by the subjects from the non commercial sector, budget organizations and non profit organizations (academic institutions, public healthcare facilities etc.), in terms of both quantity and quality of these projects.

5. The main objectives of CEBO are:
   - providing advice to potential initiators, investigators and subjects of clinical trials,
   - complex organizational support and statistical data processing of clinical trials, clinical registries and other multicentre projects, which have passed a standard and transparent approval process of CEBO, described in these organization rules,
   - development of international cooperation with foreign expert subjects in clinical trials on an international level,
   - communication with state regulation authorities in the matter of improving conditions for the realization of non commercial clinical trials,
   - further education in the area of planning, organization, data processing and interpretation of clinical trials results.

6. In the case of realization of clinical trials whose initiator would be an investigating doctor, expert association, healthcare facility or another subject, CEBO can overtake the complex responsibility as the sponsor of the clinical trial. By a contract, CEBO will ensure that the initiator(s) of the trial will retain its/their copyright on the work resulting from the clinical trial that he/they initiated.

7. CEBO has been established for a definite term, namely 24 months since its establishment. After the expiry of this period, the director of IBA, the CEBO Programme Council and the CEBO Scientific Council will jointly decide about an eventual continuation of the project, depending on its success. That decision can extend the CEBO operation under the same

conditions, or extend the CEBO operation under modified conditions, or terminate the CEBO operation.

8. For all projects initiated and organized by CEBO whose duration would exceed the potential length of CEBO existence, a decision will be made before the start of these projects about the transfer of responsibility for the completion of these projects in compliance with the original plan, with respect to the possibility that the CEBO operation should be terminated. Unless otherwise stated, this responsibility will be overtaken by IBA, while the rights of project initiator(s) will be preserved in compliance with the contractual clause(s) concluded before the start of the project.

9. In the realization of all projects, CEBO follows the legislation in force about clinical trials of drugs and personal data protection, namely:
   - **Act No. 79/1997 Coll.,** on Pharmaceuticals and Amendments to Some Related Acts
   - **Decree No. 288/2004 Coll.,** laying down details of authorization, its variations, renewals, classification for supply (legal status) of medicinal products, transfer of marketing authorizations, parallel distribution authorizations, submission and proposals for specific therapeutic programmes with non authorized human medicinal products, details of reporting and evaluating of adverse reactions to medicinal products and the way and extent of reporting of the use of a non authorized medicinal product, as amended. **(Vol. 93 of 11.5.2004)**
   - **Decree No. 472/2000 Coll.,** laying down Good Clinical Practice and more detailed conditions for clinical trials on pharmaceuticals **(Vol. 136 of 29.12.2000)** as amended by Decree 301/2003 Coll. **(Vol. 103 of 18.9.2003)**
   - **Decree No. 411/2004 Coll.,** on Good Manufacturing Practice, Good Distribution Practice, and on more detailed conditions for granting of manufacturing and distribution authorization, including the medicated feeding stuffs and veterinary autogenic vaccines, variations to issued authorizations and detailed conditions on licensing of control laboratories (Decree on Manufacture and Distribution of Pharmaceuticals) – **Vol. 133 of 13.7.2004**
   - **Decree No. 504/2000 Coll.,** on the Good Laboratory Practice in the field of pharmaceuticals **(Vol. 147 of 30.12.2000)**
   - **Decree No. 255/2003 Coll.,** on Good Pharmaceutical Practice, more detailed conditions for preparation, pre-use treatment of medicinal products, dispensing and handling of medicinal products in healthcare facilities and more detailed conditions on the operation of pharmacies and other operators supplying medicinal products **(Vol. 87 of 12.8.2003)**
   - **Act No. 101/2000 Coll.,** on the Protection of Personal Data and Amendment to Some Related Acts

10. In addition, CEBO conforms to the regulations in force of the State Institute for Drug Control (SUKL) in the realization of all its projects.

11. The seat of CEBO is Kamenice 126/3, 625 00 Brno. The seat of CEBO can be modified while all other facts in these organization rules remain valid.

Article 2
Organizational structure and management

1. The CEBO bodies are:
   - CEBO Programme Council
   - CEBO Scientific Council

The Programme Council is the main managing body of CEBO. All activities carried out as CEBO activities have to be duly approved by the Programme Council. The Scientific Council is informed regularly about the activities of the Programme Council by its Activities Report. The powers and the manner of voting of the Programme Council are described in the CEBO Organization Rules.

2. The CEBO Programme Council has the following structure:
   - chairman
   - vice-chairman for clinical trials
   - vice-chairman for other multicentre projects
   - members (important clinical experts)

3. The Programme Council meets at least once every six months in order to decide about the projects realization, to evaluate the current activities, to plan future activities and to compile a regular Activities Report. The meeting of the Programme Council can be initiated by any member of this body.

4. The Programme Council decides by means of voting (each member of the Programme Council has one vote). The chairman of the Programme Council determines whether the voting will take place during the Programme Council's meeting or will be accomplished electronically (an e-mail expression before the deadline given by the chairman of the Programme Council). At least one half of the voting members shall be present to constitute a quorum for the Programme Council. If the result of voting is unclear, the vote of the chairman of the Programme Council decides.

5. The chairman of the Programme Council is appointed by the director of IBA for a definite term, usually for one calendar year.

6. The chairman of the Programme Council can be recalled during his term of office by the director of IBA in case that serious reasons occur for this disengagement. In particular, the following cases are considered as serious reasons:
   - breaking Czech law,
   - breaking ethics rules in medical research,
   - long-term failure to meet CEBO's targets.

7. In case of recall of chairman of the Programme Council, the director of IBA is due to appoint a new chairman of the Programme Council, at the latest within 30 days of the recall of the preceding chairman.

8. In addition, the director of IBA appoints a new chairman of the Programme Council in case of the latter’s resignation, or if other facts occur that are incompatible with the function of the chairman of Programme Council.

9. Vice-chairmen and members of the Programme Council are appointed by the chairman of the Programme Council with the approval of the director of IBA. The chairman of the Programme Council recalls or appoints new members of the Programme Council after the approval of the director of IBA.

10. The Scientific Council is an advisory body of the Programme Council. The main functions of the Scientific Council involve the assessment of benefits of projects suggested for realization within CEBO, and suggesting the priorities of CEBO activities for a given period (by means of the document "Resolution on recommended goals of CEBO activities").

11. The Scientific Council involves appointed representatives of Complex Cancer Centres (CCCs) which are united within the Czech Oncological Society CLS JEP. The heads of CCCs delegate their representatives for membership in the Scientific Council following the appeal of the chairman of the Programme Council.

12. The office of the chairman of the Scientific Council is held by the incumbent chairman of the Czech Oncological Society board.

Article 3
Accounts and budget

1. The expenses to ensure CEBO activities are covered from the CEBO budget. The CEBO budget is set aside from the IBA budget and consists of three components:
   - the funds provided to IBA by third parties in order to finance the productive running of CEBO, based on transparent contractual relationships or a deed of gift,
   - special purpose funds provided to IBA by third parties in order to finance a clearly defined project, based on transparent contractual relationships, following an agreement with the initiators of the project,
   - IBA funds obtained from other sources.

2. The CEBO budget is prepared as a non deficit budget and it must cover all expenses associated with CEBO activities. The director of IBA is responsible for the CEBO budget.

3. The CEBO as a department of IBA manages only the IBA property. Handling this property is regulated by the IBA organization rules and by the legislation in force of the Masaryk University.

4. These organization rules specify and stipulate only the targets, the system of workflow and the management of CEBO. These rules are not related to any specific project(s) of CEBO. The project proposals can be made by any doctor or specialist working in the field; the CEBO Programme Council then decides about further consideration of the project. If the project has to be approved properly by the CEBO Programme Council, its realization must be based on independent contractual relationships of involved subjects in compliance with legislation in force (initiator, investigating doctors, sponsor of the clinical trial, provider of the financial resources, healthcare facilities ...). The clinical trial projects must have a sufficient budget (stipulated in a contract) which will cover the mandatory insurance of trial subjects as well.

Article 4
Human resources, bookkeeping and payroll accounting

1. In compliance with the IBA organization rules, the human resources issues of employees working at CEBO (as a department of IBA) – including personal files – are handled by the Personnel Division at the MU Rectorate in cooperation with the IBA Finance and Administration Division.

2. The bookkeeping and payroll accounting of CEBO projects is ensured by the IBA Finance and Administration Division in cooperation with the CEBO Programme Council.

Article 5
Final provisions

1. These organization rules shall enter into effect on..... , following the ratification on.....

2. The chairman of the CEBO Programme Council is charged with the updates of the organization rules. Any changes to the organization rules are subject to approval by the director of IBA.

3. The organization rules are stored at the MU Legal Division and at the IBA cost centre.

Brno, on 2006