

GENERAL REGULATIONS
OF
COMT – CENTRE FOR MOLECULAR AND TRANSLATIONAL ONCOLOGY

Art. 1 – Establishment of the Centre

The Centre for Molecular and Translational Oncology – COMT – belongs to the University of Parma and was founded pursuant to Art. 29 of the General Regulations and Art. 1 of the Regulations governing the modalities and procedures for the creation and management of University Research Centres. Hence, the hitherto outlined Regulations of the Centre are formulated in accordance with the General Regulations of the University of Parma. Constitution of COMT is approved by the Board of Directors of the University of Parma, whose resolution is reported in a corresponding Decree of the Magnificent Rector. Within the limitations provided by the General Regulations and with specific reference to the organizational, management and financial aspects, COMT acts as an independent entity governed by the hitherto defined Regulations. These are approved by the internal decision-making bodies of the Centre and by the Board of Directors of the University of Parma.

Art. 2 – Premises and Mission

COMT aims at promoting and coordinating experimental and clinical activities related to basic, applied and translational oncologic research. A central element of the COMT's activities is their potential clinical revenues and the associated technological and industrial transfers. While acquiring a wider basic knowledge and progressing through development of new and more sophisticated experimental procedures, advancing of the cancer field demands a closer cooperation between researchers with diversified backgrounds, experiences and skills. This with the purpose of optimizing the multi-disciplinary nature of the proposed actions and streamlining the potential clinical-industrial transfers. Said optimizations are not only necessary for guaranteeing the utmost competitiveness of the research carried out at the national and international level, but also to allow for the generated products to more rapidly and more effectively transferred to the cancer patient. It is believed that the full "translational" nature of the cancer research conducted by COMT may be effectively achieved in those cases where an intertwining collaboration is created between basic research groups and clinicians. Hence, the blending and merging of said complementary skills is one of the COMT's main goals.

In order to ensure the optimal intersection of research activities of a highly diversified nature, as well as encourage the possibility that these activities may lead to new ideas on valuable clinical applications, it is also necessary to find the right formulas amalgamate highly diverse lines of research and experimental approaches. Constitution of COMT may be viewed as an initial step in this direction, creating a first connection between basic research, applied research, and clinical research groups actively engaged in providing assistance to the cancer patient. COMT thus intends to act as a sponsor for the design of new multi-disciplinary research approaches aimed at generating technical-scientific products with applicative outputs in the industrial and clinical sectors. To this end, COMT strives at acting as an interface between the University of Parma and its researchers and the national and international public and private organizations that support and encourage cancer research, and/or promote the commercial exploitation of the end products of such research.

Art. 3 – Resources and Personnel

COMT pursues its goals by taking advantage of the human and financial resources and facilities granted to the Centre by the participating Departments of the University of Parma. Members of COMT may also allocate, in full or in part, research funds, funds resulting from research cooperation, licensing and service

agreements, research contracts, donations or any other type of revenue for which they are responsible, such as to warrant an effective sustainment of the Centre's operational status.

COMT may avail itself, on a temporary or more permanent basis, of technical and administrative personnel affiliated with the contributing Departments. This personnel may be assigned to the Centre on a full- or part-time basis by means of resolution of the Department's Board of Members. Moreover, COMT may avail itself of personnel undergoing training and/or hired with a fixed-term contract for the execution of specific research projects funded by the COMT. In compliance with the Italian law and the University of Parma financial regulations in force, the Centre may access the following financial resources:

- funds allocated by the Departments or University of Parma's Central Administration;
- research funds allocated by the individual members of COMT;
- research funds allocated by public or private organizations;
- donations from public or private bodies;
- revenues and royalties from intellectual property licensing or sales, service and cooperation agreements, and research contracts that the COMT may enter into with public or private entities.

For the execution of the COMT's activities, the contributing Departments make available to the Centre their instruments and laboratories, while assuring that the full accessibility of these assets remains granted to the Department's members through enforcement of specific rules adopted by the Centre. COMT is responsible for the operating, ordinary and extraordinary expenses associated with the running, servicing and maintenance of the equipment and laboratories that it accesses.

Equipment made available to COMT by the Departments may, upon request by a Member of the Centre belonging to that Department, be transferred to COMT. Such transfer remains, however, subjected to compliance with the procedures set forth by the University of Parma General Regulations and/or by the Regulations adopted by the transferring Department. The operating costs for the instrumentation and facilities taken over by the Centre from Departments shall remain a full responsibility of the Centre.

The Centre is further entitled to acquire with proper funds, or funds provided by public and private sponsors, instruments and accessories, including those that may be needed to equip laboratories, experimental facilities, animal houses and offices. COMT is similarly entitled to rent or lease equipment from public and private bodies, as well as offer for rent its equipment and facilities to public and private institutions that may have interests in pursuing independent analyses. In such case, COMT may rent single pieces, or sets of equipment, on the hourly, daily or monthly basis, or for longer periods of time, according to the adopted specific Regulations governing the modalities and costs for such renting.

Art. 4 – Duration and Offices

COMT remains active for a period of three years, starting from the date of foundation, and may be renewed for additional three-years periods by means of resolution by the Centre's Board of Directors. COMT's Administrative Offices are located within the building for technology transfer at the Parco Area delle Scienze of the University of Parma, denominated "*Laboratori di Strutture e Trasferimento Tecnologico*", whereas COMT's Directorate is located within the Department of Life Sciences.

Art. 5 – Composition

The following Departments of the University of Parma are contributing to COMT organization, management and activities:

Department of Biomedical Biotechnological and Translational Sciences (S.Bi.Bi.T.)

Department of Experimental Medicine

Department of Life Sciences;

Department of Neurosciences

Department of Surgical Sciences;

Permanent employees of the University of Parma and Associated Professors holding tenure-track positions, affiliated with other Departments than those listed above, may be nominated Members of COMT, following approval by the Centre's Board of Directors. The Professors and Technical Staff listed in the hitherto appended *Annex 1* are the founder Members of the Centre and are organized according to the Organizational Chart shown in *Annex 2*.

Art. 6 – Financial and Administrative Management

The hitherto detailed Regulations are implementable as defined by the Board of Directors of the University of Parma and the corresponding Decree of the Magnificent Rector. Any subsequent changes to these Regulations must be proposed by the COMT's Board of Directors and submitted to the University overruling Board of Directors for approval. Changes shall become effective upon the issuing of the corresponding Decree signed by the Magnificent Rector.

COMT is financially and administratively independent within the limitations of the University of Parma General Regulations in force. For administrative and accounting fulfilments, the Centre relies upon an Administrative Coordinator appointed for the purpose by the Central Administration, after having consulted the Centre's President, and central offices of the University of Parma in charge of legal and financial affairs.

Art. 7 – Organization

As delineated in the Organization Chart (*Annex 2*), the Board of Directors and the President of the Centre are the bodies responsible for adopting resolutions. The role of "Consultation Body" is played by the Technical-Scientific Committee, consisting of a minimum of 3 (three) and a maximum of 5 (five) members, usually representing by worldwide renown scientists who are not affiliated with the University of Parma, including scientists operating abroad and experts on the topics of research and/or activities carried out by the Centre. The Committee assists the President and Board of Directors in defining the Centre's strategic operational lines, in the current and annual evaluation of these activities and in the evaluation of the achievement of outlined objectives.

Art. 8 – The Board of Directors

The Board of Directors is composed of the Scientific Managers of the Operational Units that make up the Centre and/or designated representatives of these Operational Units, provided that they are formally appointed Members of the Centre. The Board of Directors is chaired by the appointed President of the Centre, while the Administrative Coordinator acts as Secretary.

The Board is responsible for the following the tasks:

- 1) duties to be undertaken during the financial year:
 - define the general outline of the Centre's activities;
 - approve contracts and agreements to be entered into with public and/or private institutions, for amounts greater than 50,000 Euros, but equal or lower than 100,000 Euros, as well as verify the feasibility and coherency of these contracts and agreements with the scope and established aims of the Centre;

- adopt resolutions on any other matter submitted for review by the President of the Centre or by other components of the Board of Directors;
- adopt resolutions regarding any proposed changes to the Centre's Regulations;

2) duties to be undertaken at the beginning of each financial year:

- define the outline, workflow and aims of the Centre's activities, normally by taking into account any suggestions or recommendations made by the Technical-Scientific Committee;
- approve the provisional budget for the following financial year;

3) duties to be undertaken at the end of the fiscal year:

- overview and approve the Annual Financial and Scientific Reports elaborated by the President of the Centre;
- approve the final financial statements;
- evaluate the degree of achievement of the predefined objectives based upon, if necessary, a separate evaluation provided by the Technical-Scientific Committee;
- identify possible corrective actions to be implemented for the pursuing of the forthcoming activities.

In case of impediment or absence of the Administrative Coordinator, the minutes of the meetings of the of the Board of Directors shall be handled by a Member of the Board, upon suggestion by the President. Said substitution must be indicated in the minutes of the meeting.

The Board of Directors appoints new Members of the Centre, with the qualified majority of at least two thirds of the Board in favour and by providing the reasons in case of rejection.

The Board of Directors is also responsible for approving the financial administration and conduction of scientific research activities supported by public or private grants, scholarships, contracts with public or private institutions, consultant contracts and conferment of assignments for professional services to individuals who are not part of the Centre.

Art. 9 – Meetings of the Board of Directors

The Board of Directors convenes a minimum of 4 (four) times per year. The Centre's President is responsible for convening the Board through a written notice. In order for the meetings to be valid, they have to be convened by means of a written convocation, transmitted by fax or electronic mail, indicating the day, time, place and the preliminary Agenda of the meeting to all members of the Board and respecting the advance notice of at least 5 (five) days prior to the date on which the meeting is scheduled.

The Board must be convened at least once before March 31th, for approving the Financial Report related to the previous Fiscal Year; before June 15th for approving the Annual Scientific Report referred to the previous year's activities and accompanied by the Research Plan for the forthcoming year; and before December 15th for approving the Provisional Budget of the forthcoming Fiscal Year. Moreover, the Board of Directors can be convened by the President for an extraordinary meeting whenever there is a need for it.

The meetings of the Board of Directors are eligible for adopting definite resolutions when at least 2/3 of the participating Members are present. Resolutions are adopted with the majority of the Members in favour, not counting the justified absentees. In case of a tie, the President's vote shall be the deciding one. In cases of renewal of the President, or in cases of unforeseen impediments, the Board of Directors is convened by the Member of the Centre with the highest academic seniority (Deputy Director).

The Administrative Coordinator or, if absent, the Secretary selected for specific meeting among its members, draws up the minutes of the meeting. The sections of the minutes containing resolutions that must go into effect prior to the next meeting. The minutes become final with the approval of the Board of Directors during the following meeting. The motions, which must be presented in writing and formulated in the

affirmative form, are approved when the number of votes in favour is greater than the sum of the contrary and abstained votes. In case of a tie, the President's vote shall prevail.

Voting is carried out in an ordinary way by the raising of hands. The secret vote is mandatorily resorted to when specifically requested by the President or by a Member of the Board.

Art. 10 – The President

COMT's President oversees and coordinates the Centre, handling the implementation of the resolutions adopted by the Board of Directors. The President is further responsible for the administrative organization and management of the Centre. He is assisted by the Administrative Coordinator, who deals with the fulfilments of administrative and accounting matters.

The President is elected by the Board of Directors with the majority of the entitled Members, stays in office for a three years mandate, and can be re-elected consecutively for an unlimited number of times.

The President is elected by means of a secret vote during the course of the Centre's first meeting after its foundation and after any renewal. In case it would become necessary to elect a new President, the Deputy Director convenes, within sixty days from the exiting President's revocation date, the meeting of the Members entitled to vote in order to accomplish the election procedure. Pending the election and appointment of the new President, the tasks normally carried out by the Centre's President are assigned to the Deputy Director.

The President designates a Member of the Board of Directors as Vice President in his/her replacement in case of absence or temporary impediment. Should said absence or impediment last longer than six months, the President automatically falls from office. In case the President resigns or terminates his office for any reason whatsoever, a new President is elected according to the procedure outlines above. In case the new President is elected within the course of the three-year mandate, the new President's shall stay in office only for the period that goes from the appointment to the end of the Centre's three-year period of duration.

The President is granted the power to represent the COMT, to chair the Board of Directors and to handle the execution of the adopted resolutions.

With the assistance of the Board of Directors, the President promotes the Centre's activities, handles relationships with the Technical-Scientific Committee, the University of Parma decision-making bodies and the Central Administration, and enforces COMT's internal Regulations.

The President is specifically responsible for:

- coordinating the COMT's activities;
- convening and chairing the meeting of the Board of Directors;
- approving contracts and agreements for amounts equal or below 50,000 Euro;
- overseeing the requests for funding and research contributions, by verifying their feasibility and coherency with the Centre's goals;
- overseeing the final accounts at the end of each fiscal year, drawing up the report on the activities carried out as well as an evaluation report on the level of achievement of the prospected objectives;
- drawing up the guidelines for the Centre's financial management;
- elaborating the annual research plan;
- delineating the budget for the following year, to be submitted to the approval of the Board of Directors, and enclosing a detailed report that illustrates the nature, source and presumed utilization of the funds.

Art. 11 – Subdivision of Resources upon disbanding of the Centre

Should the COMT be disbanded, the instrumentation, facilities and accessories made available to it by the contributing Departments shall be reassigned to the original Department. As regards the instrumentation purchased directly by the Centre, using funds specifically assigned to it and/or acquired by it, these shall be first be offered for management to the individual Operational Units that make up the Centre, and secondly to the Department to which personnel of these units belongs.

NOTA.

Gli *Allegati (Annex 1 e Annex 2)*, cui si fa riferimento nel Regolamento sopra riportato, corrispondono all'elenco del Personale ed agli Organigrammi già allegati nelle designate Sezioni del presente Manuale di Gestione.

Allegato A2 MG1.3

REGULATIONS FOR THE USE OF SINGLE PIECES OF EQUIPMENT OR ENTIRE FACILITIES

Art. 1

The purpose of these Regulations is to define the procedures and modalities for accessing and utilizing the equipment and facilities available at COMT and/or at the Departmental facilities that form an integral part of the Centre. The hitherto defined Regulations also serve the purpose to define the modes of utilization of the equipment that the Centre may access thanks to specific agreements reached with other public or private research institutions. More globally, the present Regulations aim to optimize the exploitation of said instrumental resources by individual researchers of the University of Parma, by members of the Centres/Laboratories adhering to the Regional High-Technology Network of Emilia-Romagna, and by researchers operating at public or private institutions that may have commissioned to COMT the pursuing of specific research activities.

Art. 2

These Regulations apply to the equipment and facilities listed in the *Instruments and Facilities* section of the COMT website (www.comt.unipr.it).

Art. 3

The COMT personnel responsible for managing, overseeing and operating the equipment/facilities, shall ensure implementation and compliance with these Regulations.

Direct access to Facilities and Equipments requires that the users are in possess of a proper insurance that fully covers their liability in case of accidents.

Art. 4

Each piece of instrument/facility to which these Regulations apply is identified by a code printed on a tag which is affixed to the discrete piece of equipment, or to the entrance door of the facility. An identification sheet is available for each piece of equipment/facility. This contains the following items:

- A) a thorough description of the equipment/facility and its operation procedures and modalities;
- B) indication of the position of the instruments within the facility;
- C) detailed instructions for use of the single instruments or the facility as a whole;
- D) a booking sheet;
- E) the name of the Reference person for the equipment/facility.

The identification sheet is regularly filled out and updated by the COMT personnel responsible for the equipment/facility.

Art. 5

Considering the entire set of equipment and facilities, i.e. not limited to a single piece of equipment or facility, COMT guarantees the accessibility to internal and external users¹ of its instrumental assets for a minimum number of 10 non-consecutive business days per month. The actual number of business days assured for each piece of equipment/facility to users not affiliated with COMT, or not bound to it by specific agreements, is

determined by the designated Reference person for each piece of equipment/facility and is notified upon request to the indicated users.

Direct use, in other words direct access with no prior request, to the equipment/facilities is granted exclusively to researchers affiliated with COMT², provided that they are duly qualified as defined by the Reference persons of the equipment/facilities. These individuals are prioritized for the use of the equipment/facilities which are made available to them in three different scenarios:

- 1) for the conduction of research contracts supported by specific funds provided by funding institutions;
- 2) for the pursuing of properly recognized and asserted technical-scientific cooperation agreements with public and private institutions;
- 3) through services rendered to third parties for a fee. Internal and external users may access the equipment only in the presence of the COMT's personnel or, if in possession of documentation proving that they have already been trained and/or are competent in the use of the equipment, by specific authorization issued by the Reference person of the equipment/facility. In that case, authorization to directly access the equipment or facility is granted only after the Reference person, or his/her delegated substitute, have verified the operators' actual skills and abilities.

Researchers affiliated with COMT shall be able to access the equipment/facilities, in full compliance with these Regulations, for institutional research purposes, for applied research activities, for services rendered to third parties within the framework of agreements signed by COMT, for the providing of services directly commissioned to the Centre, or by members of the Departments of the University of Parma associated with the Centre. As mentioned in **Art. 4**, Letter "D", in order to ensure unrestricted access and proper use of the equipment subjected to these Regulations, and to prevent any interference in the activities carried out by the researchers affiliated with the Centre, a booking sheet is provided for each piece of equipment/facility. These sheets are part of a logbook in which the following information must be provided by the end user:

- A) name and affiliation;
- B) scope of use (i.e. institutional research, scientific cooperation governed by a contract, or service rendered to third parties);
- C) booking date and time.

The designated Reference person and/or COMT personnel authorized to use the equipment are responsible for the filling out this sheet.

Art. 6

The Reference person of each piece of equipment guarantees that the instrumentation is kept in conditions of proper operation and arranges the scheduling of routine and extraordinary maintenance (see **Art. 3**). The Reference person is also responsible for suggesting ways of procuring financial coverage for these maintenance services by either accessing funds that the Centre may have specifically allocated to such purpose or, where allowed and/or deemed reasonable, by requesting that the costs are shared by the affiliated members of the COMT that actually make regular use of the equipment.

Art. 7

The fees for the use of each piece of equipment/facility shall be charged to the end-users according to the Rates defined in the *Instruments and Facilities* section of the COMT website (www.comt.unipr.it). These rates may vary depending upon the affiliation of the client (internal vs. external user), must be regularly updated and, in any event, reviewed every year also on the basis of the actual use of the individual pieces of equipment and facility.

Application of the user's Rates, i.e. the fee defined in advance and requested to be paid for using a piece of equipment/facility, is normally proposed by the Reference person of the equipment/facility. This means that the COMT personnel may decide, at its own discretion, to allow the equipment/facility to be used free of charge (for example within the scope of a scientific cooperation or industrial agreement). The researchers affiliated with COMT and their direct associates shall be able to consistently access the equipment and facilities

free of charge, but not independently of proper arrangements with the Reference person, as stated in **Art. 5** of these Regulations. Internal users belonging to the University of Parma and/or to the Regional High-Technology Network of Emilia-Romagna (or their associates), may access the equipment for a reduced fee, up to 50% lower than that charged to external operators. This without prejudice to special agreements, scientific collaborations formalized by means of allocated funding, or agreements through which additional funds may be accessed for the management of the equipment and facilities.

It is understood that in all other cases not listed above, the costs of all consumables and accessories that may be necessary for the use of the equipment, or that may be specifically requested by the customer, shall be charged to the user. This with the exception for material accessible by means of prior agreements entered into with members of COMT.

Art. 8

The present Regulations have been approved by the directing bodies of the University of Parma, and are available for consultation on the COMT website (www.comt.unipr.it). For additional explanations, please refer to the Centre's Director, or directly contact the single Reference person indicated for the equipment/facilities enlisted on the aforementioned website.

¹*Internal user* stands for employees of the University of Parma or personnel belonging to Research Centres and Laboratories constituting the Regional High-Technology Network of Emilia-Romagna. *External user* refers to private and public organizations, or personnel not belonging to the University Parma or any of the Centres/Laboratories constituting the High-Technology Network of Emilia-Romagna.

²The term COMT's *affiliate* refers to internal/external staff personnel enlisted in the Centre's organization chart.