**Coordinating investigator :**

***Pr Guillaume PIESSEN***

Service de Chirurgie Digestive et Générale

Hôpital Huriez – CHU de Lille

59037 Lille Cedex France

E-mail:Guillaume.piessen@chru-lille.fr

**Co-Coordinating investigator:**

***Pr Antoine ADENIS***

ICM Oncologie Digestive

208 av des Apothicaires 34295 Montpellier

E-mail:antoine.adenis@icm.unicancer.fr

**Co-Coordinating investigator:**

***Dr Florence RENAUD***

Service d’anatomie et sytologie pathologiques

Hôpital La Pitié Salpêtrière

75013 Paris

E-mail:florence.renaud@aphp.fr

**CRA : A*mine ROUBAI***

Pôle Promotion Interne

Direction de la Recherche et de l’Innovation

CHU de Lille

6 rue du Pr Laguesse

59037 Lille Cedex France

***Phone : +33 3.20.44.41.45***

***Fax : +33 3.20.44.57.11***

E-mail : ma.roubai@chu-lille.fr

**CRA coordinating :** ***Aomar KEMKEM***

Pôle Promotion Interne

Direction de la Recherche et de l’Innovation

CHU de Lille

6 rue du Pr Laguesse

59037 Lille Cedex France

***Phone : +33 3.20.44.41.45***

***Fax : +33 3.20.44.57.11***

E-mail : aomar.kemkem@chru-lille.fr

**Project manager : *Stéphanie DEVAUX***

Service de Chirurgie Digestive et Générale

Hôpital Huriez – CHU de Lille

59037 Lille Cedex France

***Phone : +33 3.20.44.55.06***

***Fax : +33 3.20.44.59.14***

E-mail : stephanie.devaux@chru-lille.fr

**ACRONYM of the project :**

**FREGAT**

*French EsoGastric Tumours : French clinico-biological database*

**Submission Form**

**For scientific research project**

**Part 1 : Submission procedure**

**Part 2 : The scientific project**

**Part 3 : Scientific expertise of the project**

***Completed file has to be sent to :***

**contact@fregat-database.org**

***Stéphanie DEVAUX***

***Project manager FREGAT***

***Phone: +33 3.20.44.55.06***

***Fax: +33 3.20.44.59.14***

**Part 1**

**Submission procedure**

**&**

**Steps of the management of scientific research project**

1. Complete the submission form exhaustively

Submission package must contain every element requested and needed for the scientific and technical evaluation of the project.

1. For academic project :
* Complete exhaustively the part 2 of this document
* If this project has funding, please provide budget grid detailed
* If the project has been evaluated by a scientific committee, please attach evaluation record
1. For industrial :
* Complete exhaustively the part 2 of this document
* Please attach the protocol with an acronym
* If the project has been evaluated by a scientific committee, please attach evaluation record
1. Project must be sent in electronic format to : **contact@fregat-database.org**

**You will be informed by email that the file is received**

1. Restricted Scientific Committee will examine the file under 30 days regarding scientific value and feasibility. After Restricted Scientific Committee’s approval, the file has to be submitted to the Scientific Committee

**You will be informed under 1 month of the Scientific Committee’s decision.**

1. Une proposition de devis vous sera adressée. Notez qu’il est important qu’un financement soit pourvu afin que le projet soit examiné puis mis en œuvre.
2. Establishment of an agreement after quotation acceptance
3. Implementation of the project

**PART 2**

**THE SCIENTIFIC PROJECT**

|  |
| --- |
| **1 -: GENERAL INFORMATION** |
| Title |  |
| Acronym |  |
| *Coordinator/Project manager (Please attach dated and signed résumé)* |
| Name – first nameTitle/Statut AddressEmail Phone |  |
| *Persons involved in the project (Please attach dated and signed résumé)* |
| Team(s)/Centre(s)Name – first nameTitle/Statut AddressEmail Phone |   |
| Partnerships : | [ ]  Academic partner[ ]  Industrial partnerIf partnership, please precise type of support brought by partner:[ ]  For multicentric projects, precise which Fregat centers are involved : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Necessary supplies (several possible answers) | Number of patients : |\_\_\_\_\_| [ ]  Blood samples [ ]  Tumoral samples [ ]  Socioeconomic questionnaires [ ]  SHS questionnaires [ ]  Quality of Life questionnaires [ ]  Clinical data  [ ]  Other: please, precise |
| Key words |  |
| Study design*(transversal, cohort, case-control, retrospective, prospective..)* |  |
| Duration of the project |  |
| Amount of funding + source |  |
| Has the project already been evaluated by a scientific committee (or peers)? [ ] YES [ ]  NO If yes, precise which one (please attach evaluation record) |
| Summary of the project with rational and hypothesis - **Maximum 5000 characters – Calibri 11** |
| **3 - SCIENTIFIC FILE** |
| **3.1. Context of the project** |
| 3.1.1. Scientific context |
| (Calibri 11) |
| 3.1.2. Position and relevance of the project regarding national, European and international context. |
| (Calibri 11) |
| 3.1.3. Publications (maximum 5) supporting the project’s interest |
| (Calibri 11) |
| **3.2. Project objectives and outcome measures** |
| 3.2.1. Primary objective |
| (Calibri 11) |
| 3.2.2. Primary evaluation criterion |
| (Calibri 11) |
| 3.2.3. Secondary objectives |
| (Calibri 11) |
| 3.2.4. Secondary evaluation criteria |
| (Calibri 11) |
| **3.3. Inclusion and non-inclusion criteria** |
| (Calibri 11) |
| **3.4. Statistical method and feasibility (evaluation of required number of samples, patients, data, statistical method choosen. To be justified)**  |
| (Calibri 11) |
| **3.5. Description and rationale of the biological resources needed** |
| (Calibri 11) |
| **3.6. Other warranties for the feasibility of the project**  |
| (Calibri 11) |
| **4 - EXPECTED RESULTS** |
| **4.1. Scientifically** |
| (Calibri 11) |
| **4.2. Regarding research structuring** |
| (Calibri 11) |
| **4.3. Other points of interest (innovation, patient quality of life, medicoeconomic advances …)** |
| (Calibri 11) |
| **5 - FINANCIAL DETAILS** |
| **TITLE OF THE PROJECT :**……………………………………………………………………………………..……………**PROJECT HOLDER (Name – First Name):** ………………………………………………………………………**Adress :** ………………………**CP- City: |\_\_\_\_|\_\_\_\_|\_\_\_\_|\_\_\_\_|\_\_\_\_|** **Phone : |\_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_/****Email :** …………………………………………………………………………………………………………………… |

**5.1. Budget table :**

|  |  |  |
| --- | --- | --- |
| **NATURE** | **DETAIL** | **TOTAL** |
| **Working time for the project** |  |  |
| **- *Physician*** |  |  |
| **- *Laboratory technicien*** |  |  |
| **- *Nurse*** |  |  |
| **- *CRA / study coordinator*** |  |  |
| **- *Methodologist*** |  |  |
| * **- *Statistician***
 |  |  |
| **NATURE** | **DETAIL** | **TOTAL** |
| **Supplies (precise quantity and cost per unit, at least)** |  |  |
| ***- Blood samples*** |  |  |
| ***- Tumor samples*** |  |  |
| ***- Socioeconomic questionnaire*** |  |  |
| ***- SHS questionnaire*** |  |  |
| ***- Quality of life questionnaire***  |  |  |
| ***- Clinical data (precise which ones)*** |  |  |
| **Working costs**  |  |  |
| ***- Medical supplies*** |  |  |
| ***- Paper stationery*** |  |  |
| ***- sending / transportation costs***  |  |  |
| ***- Travelling costs*** |  |  |
| **Other (Please, precise)**  |  |  |
|  |  |  |
| **TOTAL (€)**  |

**5.2. Nature of fundings (details about sources of funding)**

|  |  |
| --- | --- |
| Name of the organisation |  |
| Representative Name – First NameTitle : Address :Phone :Email : |  |
| Details (funding context, is there something expected in return, …):  |  |

**6 - PERSON CONTACT DETAILS TO ESTABLISH THE CONTRACT AGREEMENT**

**Person in charge of agreement (Name – first name):** ………………………………………………………………………………….

**Department :** ……………………………………………………………………………………………………………………………………………………………………………

**Adress:** ……………………………………………………………………………………………………………..……………………………………………

**CP- City : |\_\_\_\_|\_\_\_\_|\_\_\_\_|\_\_\_\_|\_\_\_\_|** …………………………………..…………………

**Phone:** ………………………………………………………………………………………

**Fax :** ………………………………………………………………………………………

**EMail :** …………………………**@**…………………………………………………………………………………………

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATE AND SIGNATURE OF THE PROJECT HOLDER:**

Made in : ……………………………….

On : ………………………………….

Signature :

*I acknowledge that access to clinical and biological FREGAT resources is regulated by the attached FREGAT charter. FREGAT Strategic Committee may refuse access and use of these resources in case the charter is not fully observed.*

**PART 3**

**EXPERTISE OF THE SCIENTIFIC PROJECT**

|  |
| --- |
|  **PROJECT TITLE :** |
| **Are the project’s objectives consistent with FREGAT’s objectives?** | [ ]  YES [ ] NO |
| **scientifiC QUALITY :** |
| **Relevance regarding oesogastric cancers’research****Advances regarding current scientific knowledge****Objectives and hypothesis definitions****Significance of expected results****Innovative nature of the project****Opening up to new research opportunities** **Interest of results through academic point of view****Originality of the project** | **1= poor, 2 = borderline,****3 = good, 4 = excellent****|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|**  |
| **Notes :**  |
| **METHODS, STRUCTURATION et FEASIBILITY OF THE PROJECT :** |
| **Matching between methodology and the objectives of the project****If it is a comparison study, are the groups comparable****Does the target population matches FREGAT population****Are bias taken into account****Project structure and logics** | **1= bad / controversial,** **2 = correct but improvable,** **3 = good, 4 = excellent****|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|** **|\_\_\_|**  |
| **Notes :** |
| **FINANCIAL EVALUATION** |
| **Appropriateness of the allocated amounts** | **1= very insufficient/underestimated** **2 = to be modified, 3 = exact****|\_\_\_|** |
| **Notes :** |

**global EVALUATION: |\_\_\_| (1= refused / insufficient, 2 = mean, 3 = good, 4 = excellent)**

**GLOBAL OPINION:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**STRONG POINTS OF THE PROJECT:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**WEAKNESSES OF THE PROJECT :**

Expertise made on : |\_\_\_|\_\_\_| |\_\_\_|\_\_\_| |\_\_\_|\_\_\_|\_\_\_|\_\_\_|

Signature of experts :

**PART 4 (reserved FREGAT team)**

**Tracking file**

Nom du projet : …………………………………………………………………………………………………………………..

Nom, prénom et coordonnées du porteur de projet : ………………………………………………………….

Organisme du porteur de projet : ………………………………………………………………………………………..

|  |  |  |
| --- | --- | --- |
| **Etape 1 : Réception du projet** | ARC ou Chef de projet (nom/prénom) | Date :  |
| **Etape 2 : Transmission pour choix du ou des examinateur(s)** | Pr. PIESSEN | Date :  |
|  | Examinateur 1 : | Date :  |
|  | Examinateur 2 : | Date :  |
|  | Examinateur 3 : | Date :  |
| **Etape 3 : Proposition de devis** | Chef de projet (nom/prénom) | Date :  |
| **Etape 4 : Etablissement d’un contrat** | Service juridique de la DRI (nom/prénom) | Date :  |
| **Etape 5 : Mise en œuvre du projet** | Data-Management (nom/prénom) | Date :  |
|  | Tumorothèque (nom/prénom)  | Date :  |
|  | CRB (nom/prénom) | Date : |