



## **RESAR Governance Committee**

TARPSWG is a spontaneous collaboration between expert health professionals interested in retroperitoneal sarcoma and fostering scientific research remains a main priority of this collaboration.

Membership for TARPSWG is open to any healthcare personnel, scientist or research personnel interested in retroperitoneal sarcoma. Request for membership is submitted through [www.tarpswg.org](http://www.tarpswg.org) and renewed annually in occasion of the Spring Semiannual Meeting. Participation to TARPSWG meetings is tracked.

One central initiative for advancement in our understanding of the optimal management of retroperitoneal sarcomas is through the **RESAR study**, a prospective observational study started in 2017, that will be utilized to answer multiple scientific questions.

Other forms of scientific collaboration of TARPSWG may include:

- interventional and randomized trials, some embedded within RESAR in the form of “trial within a registry”
- prospective / retrospective studies in cohort of patients not included in RESAR

TARPSWG scientific activity is multicentric by definition and implies that all research activities are conducted according to the good clinical practice guidelines, as well as in respect of data protection and safety international laws.

For the purposes of legal appropriateness, and to foster the research process TARPSWG agreed upon a policy of friendly relationship between participating institutions that is formally established in the

*“Agreement for Sharing and Use of Data for “REtroperitoneal SARcoma Registry (RESAR):  
prospective collection of primary retroperitoneal sarcoma  
patient’s data, radiological and pathological material”  
(Framework Agreement)*

The Framework Agreement has the aim of regulating and accelerate any contract need to perform research project in RESAR, but will be used and expanded for the general purpose of TARPSWG research activities included:

- multicentric studies performed on cohort of patients not included in RESAR
- multicentric studies performed with centralization of data different from that established for RESAR

This document establishes the role of the RESAR Governance Committee as the TARPSWG body for the functioning of the project.

### *Definitions*

**GOVERNANCE COMMITTEE:** TARPSWG body that lead RESAR and strategically responsible for shaping an overall project vision, overseeing its quality and prioritizing the study proposals submitted from time to time (also includes Executive Committee and Chair)

**CHAIR:** Lead of the Governance Committee



**EXECUTIVE COMMITTEE:** Operational group responsible for managing the regular functioning processes of RESAR project.

**RESAR PI:** Principal Investigator of the whole RESAR study

**LOCAL PI:** Principal Investigator for RESAR in each participating center

**STUDY PI:** Principal Investigator of a named project/substudy to be run within RESAR

**CRC:** Clinical Research Coordinator of the RESAR Platform

**TARPSWG:** TransAtlantic Australasian Retroperitoneal Working Group



## **GOVERNANCE COMMITTEE**

### **1. RESPONSIBILITIES**

- a. To regularly assess RESAR project's progress and its future prospects
- b. To oversee use of data stored within the RESAR database, and prioritize projects
- c. To assess the feasibility of modifying the dataset or introducing substantial amendments related to its execution
- d. To support the REC (Research Committee) in the process of new studies approval
- e. Supervision of the authorship rules for RESAR projects in conjunction with the Study PIs

### **2. COMMITTEE STRUCTURE**

- a. The committee will include up to 20 members, distributed as follows:
  - i. One representative from each of the top 10 recruiting RESAR sites,
  - ii. Up to 10 TARPSWG members, not necessarily affiliated to RESAR recruiting sites, to guarantee inclusive representation of the Working Group. These members are coopted by the representatives of the top recruiting RESAR sites, after the call for application launched by the Chair.
- b. Participation in the Committee can be renewed as long as the requisite in that position is kept for point 5.a.i), and can be renewed for 2 mandates for point 5.a.ii)

### **3. ORDINARY FUNCTIONING**

- a. The committee will meet in teleconference quarterly



## **EXECUTIVE COMMITTEE**

### **4. ROLE**

- a. To oversee the functioning of the RESAR project
- b. Coordinate new center activation, contracting issue, RESAR platform access.
- c. To oversee the monitoring of data quality
- d. To keep Local PIs informed about the progress of the study and to update the mailing list of Local PIs

### **5. COMMITTEE STRUCTURE**

- a. The committee will include up to 10 members, distributed as follows:
- b. up to 8 TARPSWG members, with a 4 year term and with possibility to be renewed; they are nominated on a voluntary basis after a call by the Chair
- c. The RESAR Platform Clinical Research Coordinator (CRC)
- d. Chair of the Governance Committee
- e. The Executive Committee is fully part of the general Governance Committee, and members can sit in both.

### **6. TASKS**

- a. The Executive committee will meet by teleconference every 2-3 month to coordinate activities



## **RESAR GOVERNANCE COMMITTEE CHAIR**

### **7. ROLE**

- a. To Chair the general Governance Committee and the Executive Committee
- b. Responsibility in the contract process on behalf of the TARPSWG for all those matters in which RESAR and its Framework Agreement are concerned.
- c. To organize RESAR Investigators' Meeting at least twice per year, not necessarily in occasion of TARPSWG Semiannual Meeting
- d. To launch call for nominees for the Executive Committee every 4 years (see point 5.b)
- e. To launch call for application to the Governance Committee every 4 years (see point 2.a.i, 2.a.ii)
- f. The Chair will be in charge for 5 years, and will be nominated among the members of the Governance Committee, and can be renewed

### **8. TASKS**

- a. The Governance Committee Chair will be in charge of final approval of new sites to RESAR
- b. The Governance Committee Chair will notify the RESAR CRC once a new site has obtained local IRB approval and joined the Framework Agreement in order to let the CRC releasing the secured login credentials the new participating sites investigators
- c. The Governance Committee Chair will be responsible for contract relationships with the Legal Offices of the participating institutions
- d. The Governance Committee Chair is in charge of coordinating with the REC Chair to have the evaluation process of projects working; he/she will also have to nominate a mentor for each project evaluation among the Steering Committee members



## RESAR SITE STRUCTURE

9. Each RESAR site should identify a Local PI and report this to the Governance Committee Chair
10. Additional Investigators from each site should be communicated to Governance Committee Chair and RESAR CRC, along with request for login credential to the RESAR Platform
11. Each Local PI will be inquired by the CRC when a new study project is launched within RESAR study, and will have to declare whether the single RESAR site will **opt in or opt out** for participating in the named project.
  - a. Once a RESAR site has opted in for a named project, it is responsibility of the Local PI to ensure that all needed quality checks and/or adjunctive data collection are completed, under the guidance of the Executive Committee
  - b. Reasonable deadlines will be established by Study PIs and CRC to meet requested data queries for named projects, after that the Local PI will be notified if the site participation to the project has to be withdrawn to ensure adequate timelines in the interest of the whole RESAR project
12. If the Local PI will change, the Governance Committee Chair and the CRC must be advised of the change
13. In case a new Local PI will succeed to the previous one, it will be responsibility of the Governance Committee Chair to agree with the new Local PI upon authorship privileges for ongoing RESAR projects and publications.