

The Long-term Ovarian Cancer  
Survivor Project  
*A Department of Defense Initiative*

PI: Michael Birrer

Co-PI: Lari Wenzel

GOG Chair: Philip DiSaia

Advocates Chair: Mary Scroggins

# Overall Grant Structure

- Phase I

- Two years grant
  - Awarded to three teams
- Build consortium
  - Establish function network
  - Demonstrate effective communication
  - Engage advocates
- Obtain initial data

- Phase II

- 5 year grant
  - One award
- Use consortium to obtain definitive data
- Written and oral presentation for application

# Why am I still alive?

What is different about long-term (10 years) survivors

Is it something about the patient or the tumor or both?

What are the long-term consequences of the diagnosis and treatment of ovarian cancer

# Specific Aims

- To determine the genetic and immunologic features of Long Term versus Short Term survivors
- To validate a genetic signature that predicts for recurrence of early-stage, high-grade EOC
- To determine the extent to which health-related QOL measures, additional PROs, and key CTCAE criteria predict LT OC survival.
- To examine, as an exploratory aim, the potential relationship between health-related QOL, PROs, and key CTCAE criteria and genomic features predicting disease recurrence.

# Scientific Collaborators

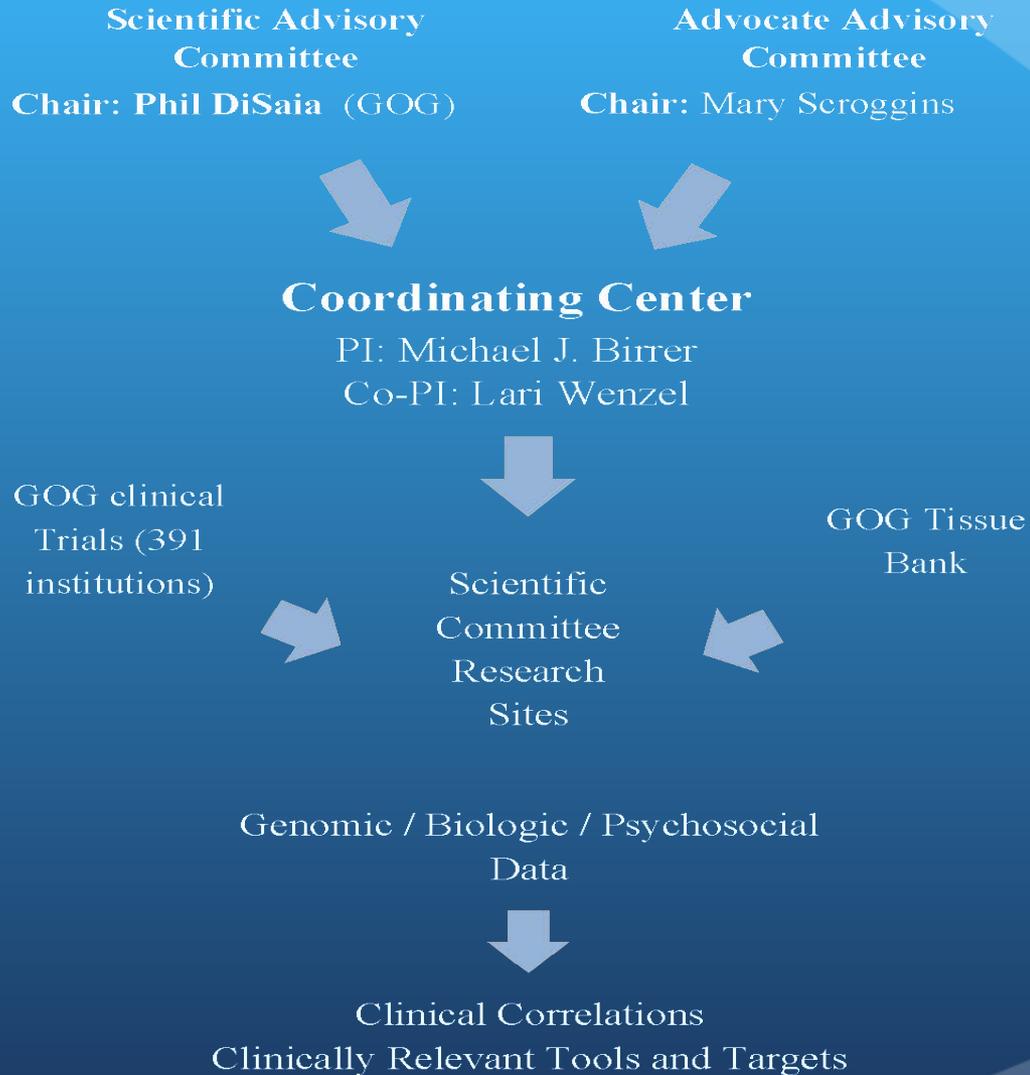
- Tumor Analysis

- Michael Birrer: expression profile
- Samuel Mok: miRNA
- George Coukos: immune biomarkers
- Kenneth Nephew: epigenetic
- William Hahn: genomic
- Giovanni Parmigiani: statistics

- QOL Analysis

- Lari Wenzel: QOL study design
- David Cella: QOL study design
- Mark Brady: GOG QOL data

# Whole Consortium Structure



# Advocates Advisory Board

How do we reach out to patients that are not in GOG clinical trials?

How do we engage the patients to be available today and in the future?

How do we sensitize the community to this expensive and long study?

# AAB Role

- Advise on issues of importance to LT survivors
- Develop/implement steps to promote consortium visibility
- Assist in recruiting study participants; lead in developing consumer educational material (e.g., brochures, fact sheets, online resources)
- Advise on/assist in developing appropriate approaches to engage multiple populations, including outreach to vulnerable groups,
- Oversee development of informed consent documents
- Interact at consortium research sites through calls, in-person meetings, etc
- Contribute to the scientific research and progress of the consortium (e.g., assist in biomarker review/selection to ensure clinical relevance)
- Assess progress through tailored tools, research team discussions
- Expand the literature on LT OC survival and survivorship and/or on advocate involvement in research (document the process as a best practice model) by publishing a project-related article.

# Current Work Flow

## MGH and UCI

- Bi-monthly calls with GOG
- Monthly calls with AAB
- Non-GOG patient recruitment and engagement
  - Develop QOL collection and analysis tools
- Coordinate tissues molecular analysis with research sites

## Leadership

Michael Birrer, PI  
Lari Wenzel, Co-PI  
Mary Jackson, AAB Chair

## GOG

- Identifies potentially available tissues and data
  - Develops protocols for collection and distribution of material
- Biostatistical analysis of QOL
- Collects and processes tissues for distribution

## AAB

- Advertizes and educates the patient community for this project
- Identifies non-GOG patients to be recruited
  - Supports development of consent forms and other IRB material

# Macrodissection - example

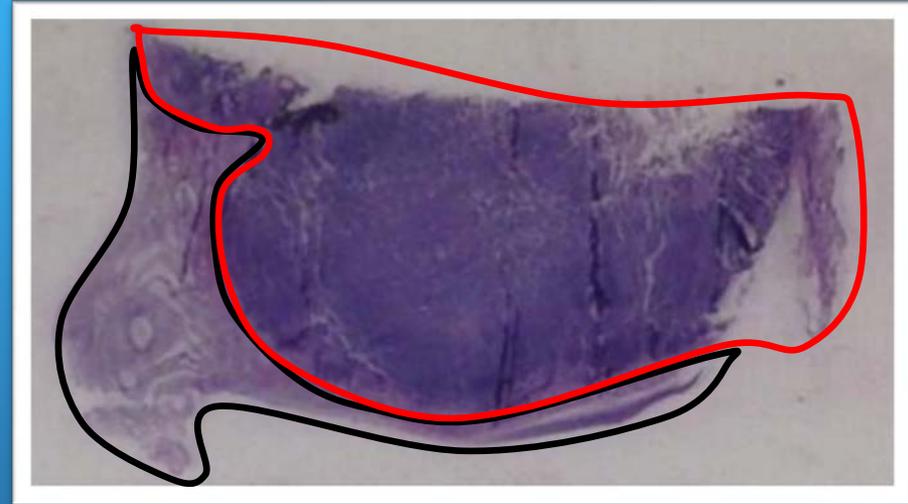
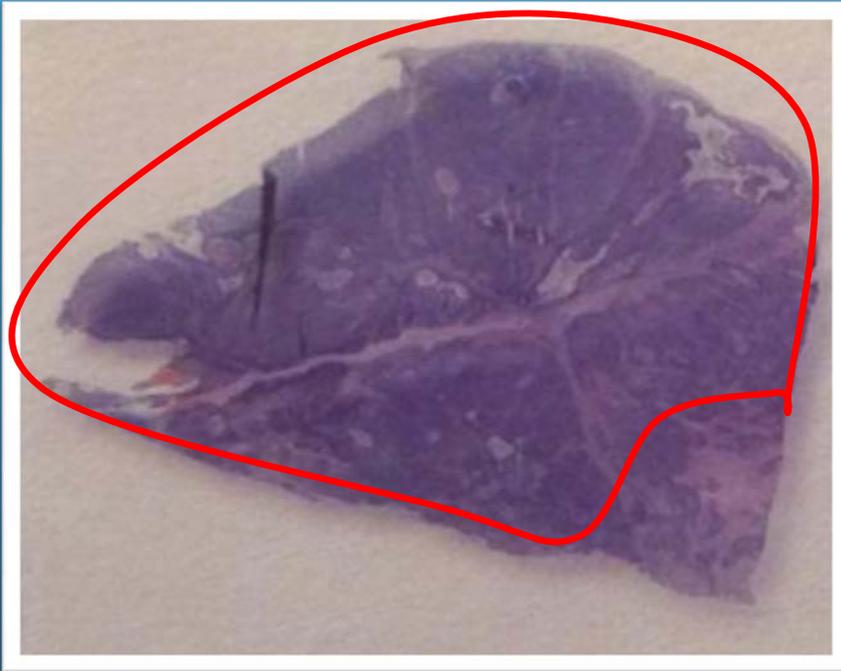


Figure 1 A and B

**Figure 1.** Cresyl violet guided macrodissection to enrich tumor component (circled by red line) and stromal component (black line, when feasible). Deparaffinized and rehydrated FFPE tumor sections were briefly dipped into 0.5% (v/v, dissolved in 50% EtOH) cresyl violet for 30 seconds. Excessive dye was washed sequentially by 70% and 90% EtOH. Sections were then dehydrated in 100% EtOH and air-dried before macrodissection using a sterile, RNase-free scalpel.

# AAB Key Project Goals

- Recruit new Patients through AAB
- Publish review on AAB role in project
- Create social media community for long-term survivors

# AAB Activity Results

## AAB members activity:

- Created advertizing material to be distributed on social media, foundations web sites, survivors' events
- Provided a list of events where we should be present and advertized the project through their direct participation
- Maintain regular social media advertisement using the social media network organized by ovarian cancer foundations and healthcare groups
- Contributed to development of QOL survey and IRB protocol
- 2 members eligible for the study participated in QOL survey and interview

**We are in touch with 65 patients identified by AAB  
10 of them are fully enrolled**

# What We Need from You to Enter Phase II:

- 1) Written support: collaboration letter for Phase II
- 2) Estimate of material available (QOL data, tumors, trials etc)
- 3) Engagement of advocates
- 4) Plan for regulatory requirements