DONOR INTERVENTION RESEARCH ACOT WORK GROUP

ACOT Meeting
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David A. Gerber, MD

Professor and Chief
Division of Abdominal Transplantation
Department of Surgery
University of North Carolina at Chapel Hill

Organ Quality Limits Transplant Outcomes

- Insufficient ideal donors; increase in DCD, marginal and expanded criteria donors
  - Donor quality defined by post-transplant outcomes according to risk of graft loss (patient death or need for retransplantation)
- Inferior organ quality engenders ***recipient*** morbidity and mortality

The Need for Innovation and Research in Donor Intervention and Treatment

- To increase the number of organs available for transplantation
  - Mitigate waiting list candidate morbidity and mortality
- To improve the quality of organs used for transplantation
  - Mitigate recipient morbidity and mortality

Obstacles to Research and Innovation in Deceased (Brain Dead) Donors

- Scientific
- Ethical
- Logistical
- Regulatory

Constituents:

Investigator

Donors / donor families

Donor hospitals

Organ Procurement Organizations

OPTN

Waiting list candidates

Transplant recipients / centers

Problem

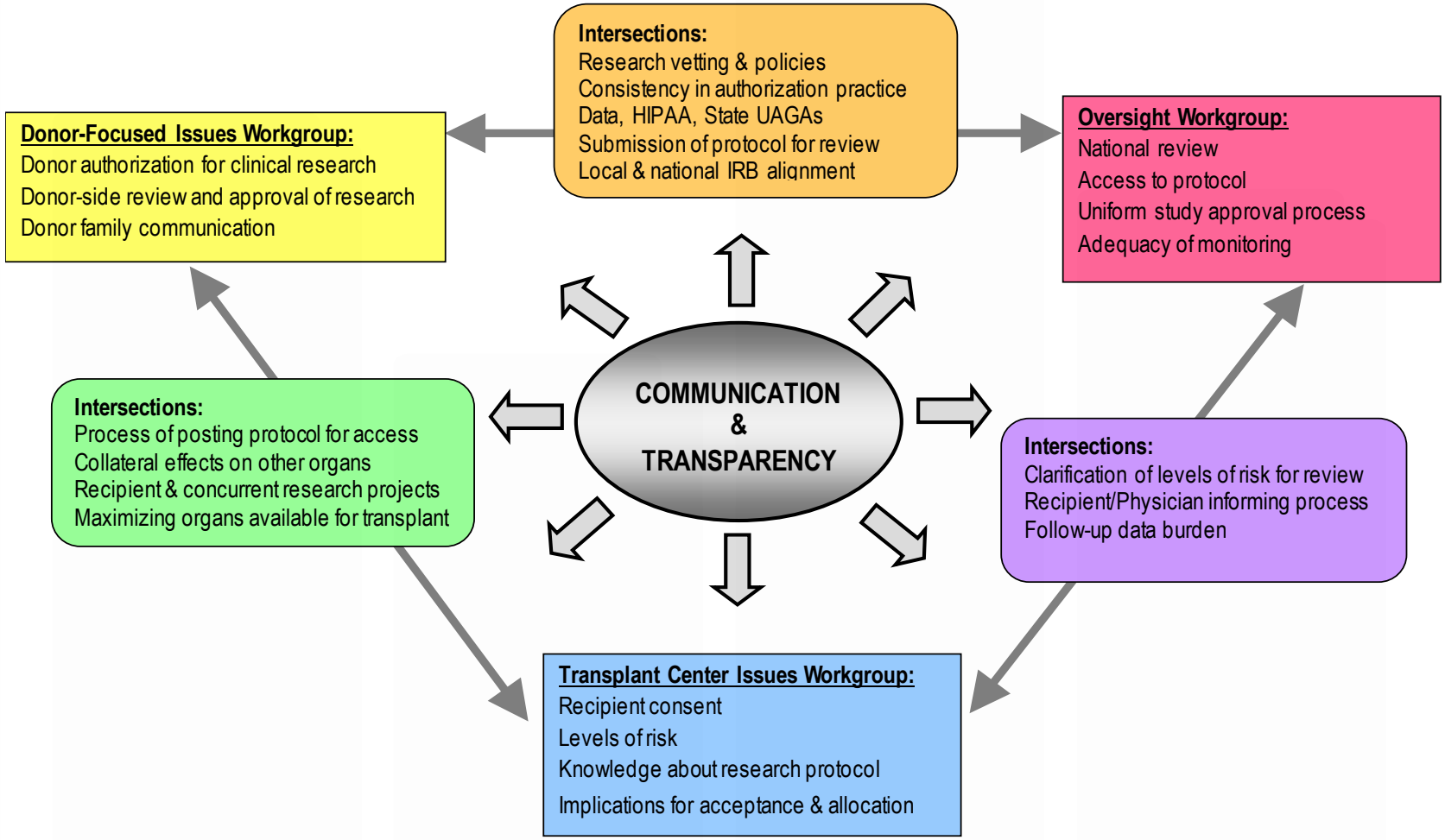
- Current infrastructure is inadequate to support effective donor intervention and treatment studies.

The *magnitude and complexity* of the challenges require guidelines/processes to facilitate the optimal design and safe execution of clinical trials in deceased donors.

Donor Intervention Research ACOT Work Group: Key Focus Areas

- Protocol and Oversight:
  - Key elements
  - Sharing
- Donor-Focused Issues:
  - Donor authorization for research
  - Ethical considerations
- Transplant Center/Recipient Issues:
  - Risk
  - Consent

Donor Intervention Research Issues Overview



Specific Actions to be Considered

- Identify existing mechanisms, pathways, etc. and alternative pathways that could facilitate unique donor-related research activities

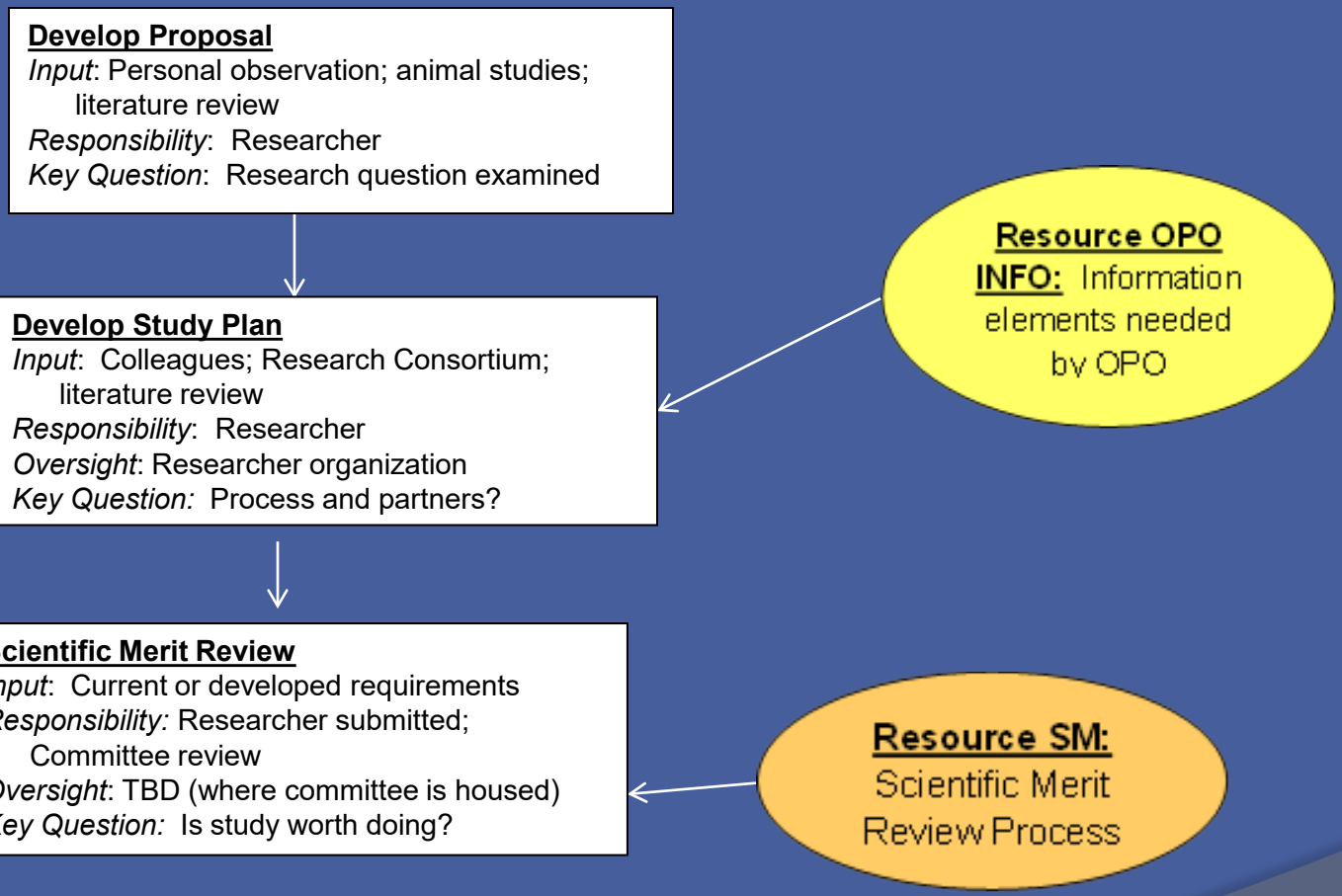
Donor Intervention Research ACOT Work Group: Key Focus Areas

- Protocol and Oversight:
  - Key elements
  - Sharing
  - Possibility of housing an IRB-type entity within the OPTN is under review and consideration
- Donor-Focused Issues:
  - Authorization for research
  - Ethical considerations
- Transplant Center/Recipient Issues:
  - Risk
  - Consent

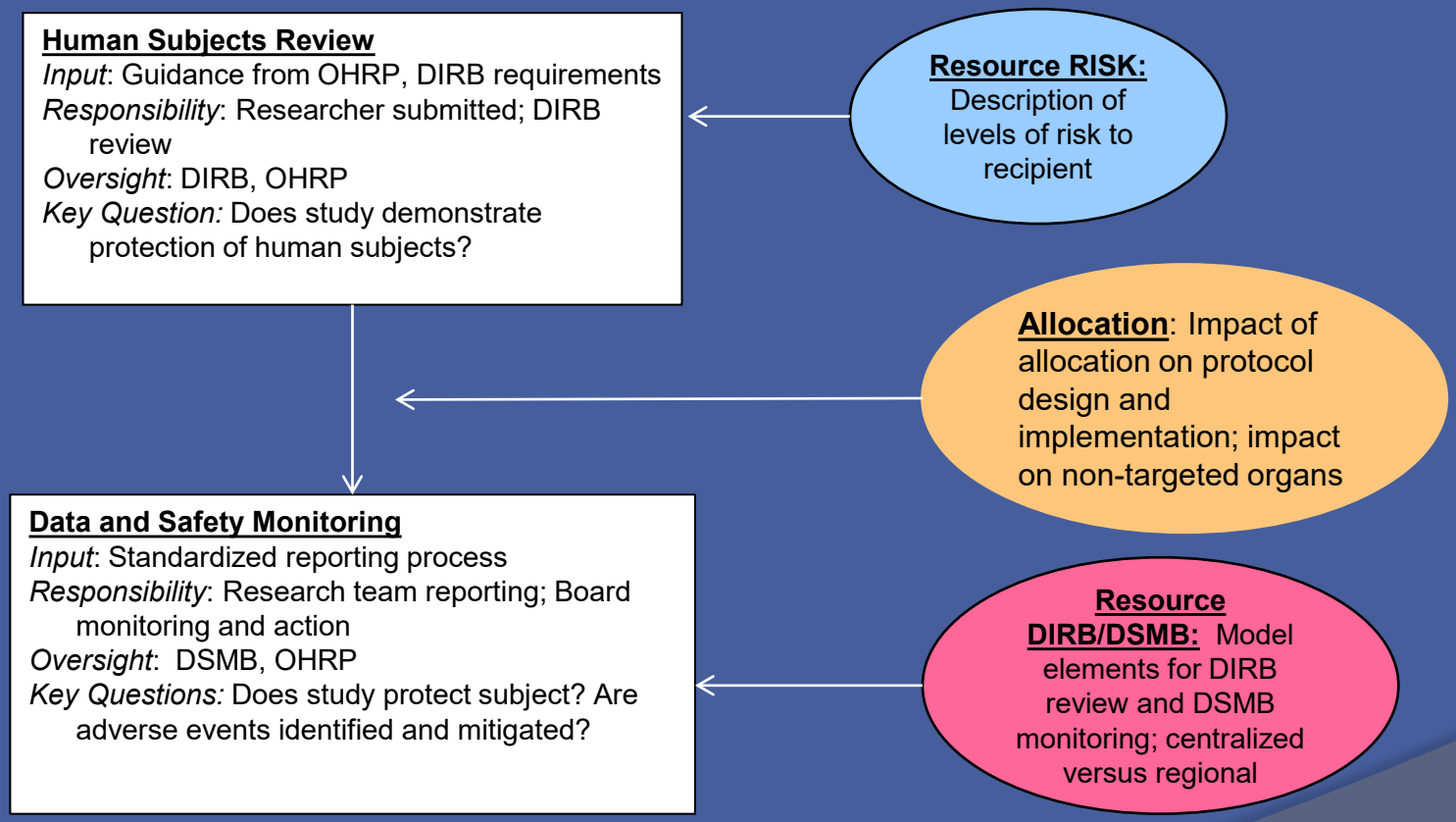
Donor Intervention Research ACOT Work Group

- Point of emphasis needs to be on big science with respect to guidance.
  - This strategy would allow the development of processes that capture all potential donor-related research activities.
- Complementary efforts are ongoing with IOM
  - Recent acknowledgement that there is funding for IOM planning meeting
  - Timeline for IOM study

Donor Intervention Research ACOT Work Group—Potential Protocol Process



Donor Intervention Research ACOT Work Group: Potential Protocol Process (Cont.)



Topics Addressed

- Donor-focused issues
  - Authorization under UAGA – dual purpose of transplant and research
  - Standards for OPO review and participation
  - Donor hospital considerations
- Transplant-focused issues
  - Quantifying risk
  - Communicating info about protocol to accepting team – required elements
  - Informed consent of recipient or possible waiver of documentation of informed consent

Developing a Recommendation

- Points of Focus
  - Logistical Issues
  - Oversight/framework
- OHRP and request for secretarial waiver for IRB review
- Prioritization of donor-related research activities
  - HHS support system developments that facilitate donor intervention research
  - Decouple funding from process for research