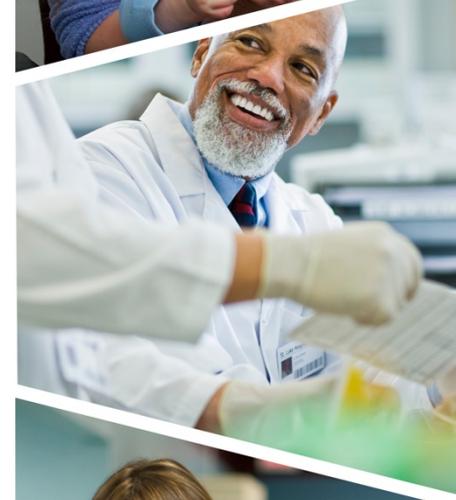


Director's Update

Recombinant DNA Advisory Committee December 2016

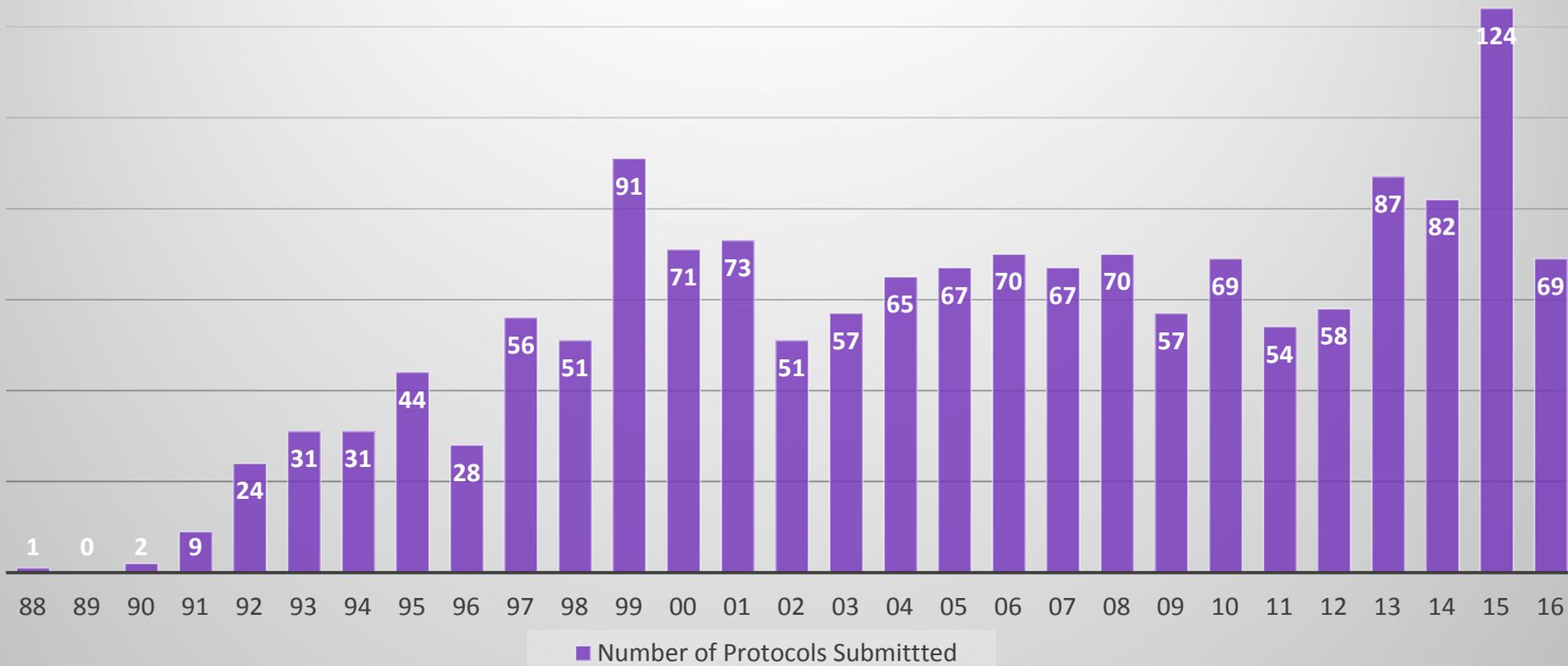
Jessica Tucker, PhD
Director, Division of Biosafety,
Biosecurity, and Emerging
Biotechnology Policy



Protocol Submissions by Year

As of November 2016

Total: 1559



Protocols submitted to OSP for registration since the June 2016 RAC meeting

24 total submissions

- Registration of 21 of the 24 protocols did not require RAC review
- Five of the 21 that did not require RAC review had a recommendation for RAC review from at least one oversight body
- Three of the 24 will be reviewed at this meeting
 - ❑ These three will employ “off-the-shelf” allogeneic T cells transduced with lentiviral vectors expressing different CARs
 - ❑ At least one oversight body requested RAC review for each of these three protocols

Protocols submitted for registration since the June 2016 RAC meeting (cont'd)

- **Protocols completing the registration process without RAC review include:**

Diseases	
15 Oncology	1 Peanut allergy
1 Monogenic disease	2 Infectious disease
2 Age-related Macular Degeneration	

Vectors		
3 Lentivirus	3 Adenovirus	3 AAV
7 Retrovirus	2 Plasmid	3 Listeria

RAC Review and In-Depth Discussion of Three Protocols

- **First protocols selected for review under the new process in the amended *NIH Guidelines***
 - Requests for review from Institutional Biosafety Committees and/or Institutional Review Boards
 - NIH concurred that criteria were met
- **Protocols share multiple common elements that were sufficiently novel that these protocols and the field would benefit from RAC review and broad discussion**
 - **First use of “off-the-shelf” allogeneic T cells for chimeric antigen receptor (CAR) T cell immunotherapy**
 - New approach in a rapidly advancing field
 - Limited safety data
 - First use of gene editing mediated by TALENs
 - First use of this suicide mechanism

40th Anniversary of the *NIH Guidelines Workshop*

- **Tentatively planned for late Spring 2017**
- **Celebration of the history of the *NIH Guidelines* and the RAC**
- **Examination of the NIH's current biosafety oversight framework**
 - **Consideration of application to emerging technologies**
 - **Evaluation of gaps and duplications with other systems of oversight**
- **Envision the future of biosafety oversight**
 - **Input from stakeholders in the scientific and oversight communities and the public**