



Tab 2191	<p>OBA Summary  OBA Letter to PI on RAC Public Review  Outcome of Preliminary RAC Review  Reviews From Aguilar-Cordova, King, Markert, Mickelson,  and Fung  Sponsor's Response</p>
9 55 AM	<b>BREAK</b>
10 10 AM	<p><b>Optimization of HIV-1 Vectors Containing an Anti-HIV Antisense Payload for Gene Transfer into HIV-Infected Individuals</b>  Boro Dropulic, Ph D , Chief Scientific Officer, VIRxSYS</p>
Tab 2192	Presentation by VIRxSYS
10 40 AM	<p><b>Discussion of Risk Group Designation for Strain B of <i>E coli</i></b>  Claudia Mickelson, Ph D , RAC Chair  Dale Ando, M D , RAC Member</p>
Tab 2193	Strawman Proposal Risk Group Designation for Strain B of <i>E coli</i>
11 10 AM	<p><b>Proposed Action to Amend the NIH Guideline Requirements for Serious Adverse Event Reporting (SAER) RAC Discussion and Vote</b>  Ruth Macklin, Ph D , Chair of SAER Working Group</p>
Tab 2194	<p>December 12, 2000, <i>Federal Register</i> Notice  Summary and Analysis of Public Comments  Summary Table of Public Comments  Synopsis of Public Comments</p>
11 50 AM	<b>Public Comment</b>
12 15 PM	<b>LUNCH</b>
1 15 PM	<p><b>Discussion of Human Gene Transfer Protocol #0101-445 entitled Clinical protocol for wild type p53 gene induction in premalignancies of squamous epithelium of the oral cavity via an adenoviral vector</b></p>
PI	Gary Clayman, M D , University of Texas, MD Anderson Cancer Center
Sponsor	Introgen Therapeutics, Inc
RAC Reviewers	<p>Xandra Breakefield, Ph D  Louise Chow, Ph D  Estuardo Aguilar-Cordova, Ph D  Ruth Macklin, Ph D</p>
<i>Ad hoc</i> Reviewer	Carter Van Waes, M D , Ph D , National Institute on Deafness and Other Communication Disorders, NIH

- Tab 2195 Protocol
- Tab 2196 OBA Summary  
OBA Letter to PI on RAC Public Review  
Outcome of Preliminary RAC Review  
Reviews from Breakefield, Chow, Aguilar-Cordova, Macklin,  
and Van Waes  
Sponsor's Response
- 2 30 PM **BREAK**
- 2 45 PM **Proposed Plan for Addressing Issues Related to Institutional Biosafety Committees**
- Tab 2197
- 4 15 PM **Data Management**  
Jay Greenblatt, Ph D , RAC Member
- Tab 2198 Protocol List  
Protocols Not Requiring Full RAC Review  
Serious Adverse Event Summary Report  
Serious Adverse Event Comprehensive Report  
Amendments and Update Summary Table
- 4 30 PM **Food and Drug Administration's Proposed Disclosure Rule Highlights and Reasoning**  
Philip Noguchi, M D , Director, Division of Cellular and Gene Therapies, CBER, FDA
- Tab 2199 January 18, 2001, *Federal Register* Notice  
Presentation by FDA
- 5 15 PM **Adjournment**  
Claudia Mickelson, Ph D , RAC Chair

\* Draft meeting agenda as of 2/23/01 Please check the OBA Website for updates Times are approximate and subject to change