

CHIMPANZEE RESEARCH USE PANEL

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Today's Presentation

- ❑ Background Leading to the January 22, 2013 CoC Vote to Accept the Council Working Group Report
- ❑ NIH's Decision to Establish the Chimpanzee Research Use Panel (CRUP)
- ❑ Discussion and Vote to Establish CRUP

Summary Timeline



BACKGROUND

The IOM Report

- In December 2010, the NIH asked the IOM to review the current use of chimpanzees in NIH-funded biomedical and behavioral research.
- The IOM committee focused its efforts on the nearly 700 chimpanzees owned or supported by the NIH.
- On December 15, 2011, the IOM issued a report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*, summarizing the committee's findings.
- In this report, the committee identified three principles to serve as the basis for its criteria for assessing the use of chimpanzees in biomedical and behavioral research.



The IOM Report: Principles

1. *The knowledge gained must be necessary to advance the public's health;*
2. *There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects; and*
3. *The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats.*

The IOM Report (continued)

- The IOM concluded that “*while the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary.*”
- The committee also stated that the following areas might continue to require the use of chimpanzees:
 - some ongoing research on monoclonal antibody therapies; research on comparative genomics; and noninvasive studies of social and behavioral factors that affect the development, prevention, or treatment of disease.

Council Establishes Working Group

- In December 2011, the NIH accepted the IOM committee's principles and criteria.
- In February 2012, the CoC voted to establish the Council of Council's Working Group on the Use of Chimpanzees in NIH-Supported Research.
- NIH charged the Working Group in February 2012.

Council Working Group Charge

- Developing a plan for implementation of the IOM's guiding principles and criteria;
- Analyzing currently active NIH-supported research using chimpanzees to advise on which studies currently meet the principles and criteria defined by the IOM report and advising on the process for closing studies if any do not comply with the IOM recommendations;
- Advising on the size and placement of active and inactive populations of NIH-owned or -supported chimpanzees that may need to be considered as a result of implementing the IOM recommendations; and
- Developing a review process for considering whether potential future use of the chimpanzee in NIH-supported research is scientifically necessary and consistent with the IOM principles.

Final Council Report

28 Recommendations:

- **Ethologically Appropriate Physical and Social Environments:** defined as “environments that not only allow, but importantly, promote the full range of natural chimpanzee behaviors”. 10 recommendations.
- **Size and Placement:** assessed future research needs and colony size and placement of NIH-owned and -supported research chimpanzees. 9 recommendations.
- **Review Process:** suggested process for considering whether future research proposals using chimpanzees are consistent with the IOM principles and criteria. 9 recommendations.

Council Discussion and Actions

✓ Noted several concerns

- ✓ About the optimal placement of the CRUP, suggested that NIH determine the best location
- ✓ Regarding ad hoc members, emphasized the importance of including expertise in the research area being considered, e.g. hepatitis
- ✓ Avoid potential confusion of the roles of scientific review and CRUP review
- ✓ A determination that the research is *ethical* in human subjects does not mean the research would be *approved* in human subjects

✓ Accepted report

Council Discussion and Actions (continued)

- ✓ Dissolved the Council Working Group
- ✓ Transmitted report to the NIH. The agency:
 - ✓ Issued a Request for Comment
 - ✓ Received over 12,500 public comments
 - ✓ Prepared a response and issued its decisions in June 2013

THE CHIMPANZEE RESEARCH USE PANEL (CRUP)

NIH Decision Regarding CRUP

The NIH partially accepted what the Council proposed, making slight revisions to the name and process.

CRUP Composition (not full text)

- Replace Interagency Animal Model Committee with the independent Chimpanzee Research Use Panel to advise on use of chimpanzees in NIH-supported research.
- Members include individuals with scientific, biomedical, and behavioral expertise to evaluate whether requests are consistent with the IOM principles and criteria.
- The Council report also notes other areas of expertise – veterinarian, primatologist, bioethicist, statistician, community members.

NIH Decision Regarding CRUP (cont'd)

CRUP Process (not full text)

- Investigators proposing research using chimpanzees must submit supplemental information that addresses the IOM principles and criteria. Decision tree is included in the Council report.
- Proposed animal numbers and group sizes must be statistically or scientifically justified.
- This additional information is not needed if the research is “exempt”, for example:
 - stored biomaterials, samples from regular veterinary exams;
 - observational/non-interventional studies and no contact or interference with the chimpanzee; and
 - Noninvasive sample collection from the wild and no contact or interference with the chimpanzee.

NIH Decision Regarding CRUP (cont'd)

Placement of CRUP Consideration (not full text)

- Separate from standard reviews by agency, focus on consistency with IOM principles and criteria
- Held after standard review process for grants, contracts, intramural projects, and third-party projects
- Consideration based on supplemental information provided by investigators
- Requires majority vote of all members

VOTE TO ESTABLISH THE
CRUP

Charge to the CRUP Working Group

“The charge of the Council of Councils Chimpanzee Research Use Panel is to consider whether requests to the NIH to use chimpanzees in research are consistent with IOM principles and criteria and to provide their findings to the Council of Councils for further consideration.”

Composition of CRUP

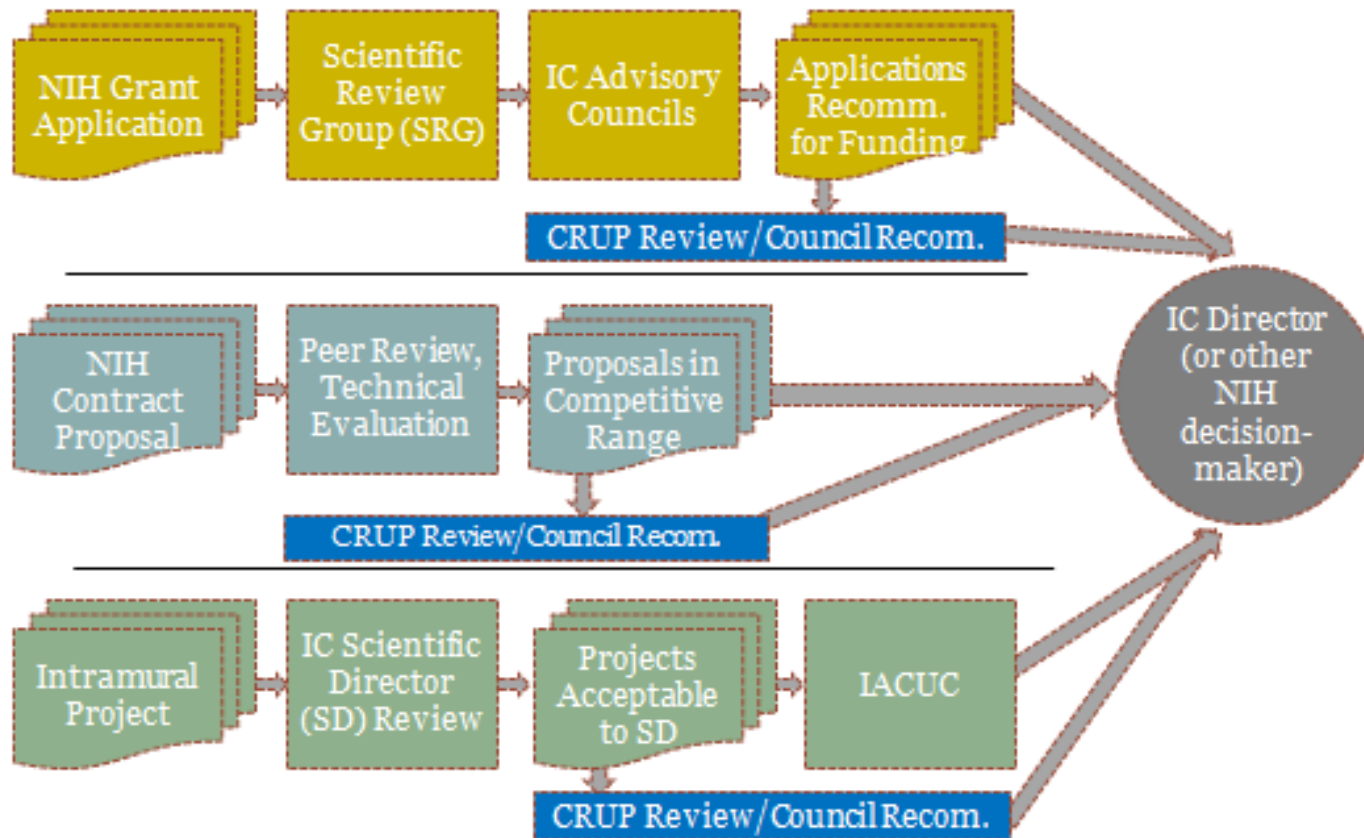
CoC Co-chairs: Dr. Gilbert C. White, II and one other

Members to include:

- Scientific experts
- Veterinarian with experience in care of non-human primates, preferably chimpanzees
- Primatologist or someone with similar expertise in primate (preferably chimpanzee) behavior.
- Bioethicist or someone with bioethics experience and expertise
- Statistician – power analysis
- And two or more public representatives
- Ad hoc members – will be added based on science in the application

NIH officials will advise on process issues and provide information but will not be members of the Panel.

Where Does CRUP Review Fall?



Dark blue boxes indicate CRUP review.

What to Expect from the CRUP

- Anticipate the CRUP will meet in person 3 times/year after IC Advisory Council meetings.
- CoC will receive the CRUP's recommendations and consider their findings 3 times per year.
- Recommendations will pertain to requests for research using chimpanzees in:
 - NIH grants and contracts
 - NIH intramural research
 - 3rd party requests to use NIH-owned chimpanzees.
- The CoC's recommendations will inform NIH leadership.

DISCUSSION AND VOTE TO ESTABLISH CRUP
