

This protocol is a renewal of previously approved IACUC protocol 2002A0162.

**Description:** The purpose of this study is to develop more effective pancreas transplantation methods in order to treat diabetes. This study will use 59 macaques and 276 mice.

The protocol was accessible to all Committee members on 17 November 2008. The protocol was referred to Full Committee because it involves the use of non-human primates.

The primary reviewers for this protocol were Dr. Wallace, Dr. I. Davis, Dr. Weinstein, Dr. Smith, and Dr. Bergdall.

**Key Points:**

The Animal Use Protocol entitled "Islet Isolation and Allograft Transplantation in Non-Human Primates" **REQUIRES FURTHER INFORMATION:**

1. Please indicate the final disposition of the mouse breeders.
2. The Committee recognizes that good experimental design often includes several control groups as described in this protocol. However, the Committee has concerns as to whether all of the control groups are necessary, especially the pancreatectomy with no treatment group. Given that some of the controls are duplicative of previously published work and that legal mandates require the Committee to ensure that the minimal number of animals necessary are used in research, please provide the Committee with additional scientific justification for the control groups.
3. Please provide a justification for group sizes based on a power analysis or reference to the literature outside of your working group.
4. Please indicate the frequency of weighing of mice in the early removal criteria.
5. Please indicate the benchmark against which the weight loss in mice will be measured.
6. The Committee understands that several animals are currently on the protocol that this new one will replace. Are animals that will be transferred from the old to the new protocol included in the numbers of animals requested? If not, how many animals will be transferred?

**Requirement to be included in this protocol:**

1. The Institutional Biosafety Officer has determined this protocol involves the use of chemical hazards and requires an updated Chemical Hygiene Plan. Please provide a letter from the Institutional Chemical Hygiene Officer indicating this requirement has been fulfilled. Please contact EH&S at 292-1284 and ask for a member of Research Safety if you require additional information. The following agents were listed in the submitted protocol, but were not listed as being a part of the Chemical Hygiene Plan for the Principal Investigator:
  - a. Ibuprofen
  - b. D-luciferin

**The further information listed above will be evaluated for approval, or need for further information by the following reviewer: I. Davis, Weinstein, Smith, and Bergdall**

The protocol received an Institutional BioSafety Assessment on 17 November 2008.

- The protocol does require a Chemical Hygiene Plan.
- The protocol does require IBC review, but is covered by IBC protocol 2007R0032.

(USDA Code: 4D)

Voting Members Present: 13; For: 13; Opposed: 00; Abstained 00; Non-Voting Alternates 01