



## Inspection Report

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THE INTEGRA GROUP

Customer ID: **36177**

Certificate: **41-R-0075**

Site: 001

INTEGRA RESEARCH FACILITY

4129 85TH AVENUE NORTH

Type: ROUTINE INSPECTION

BROOKLYN PARK, MN 55443

Date: Apr-13-2010

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No noncompliances identified on this inspection.

Inspection conducted with Vice President of Medical Research, Director of Regulatory Affairs, and Vice President of Preclinical Research.

End of report.

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**Prepared By:**

DEBRA M SIME, D V M                      USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER Inspector 1072

**Date:**

Apr-13-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

Apr-13-2010

**Title:**



## Inspection Report

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THE INTEGRA GROUP

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### 2.31 (e) (3)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: A complete description of the proposed use of the animals.

A review of protocol #08-11-2 and relevant records revealed that the procedures actually performed on the animal included an evaluation of a product on two organs instead of the one organ as described.

The facility failed to ensure that a complete description of all procedures going to be performed on animals in research are described fully in the protocol submitted to the IACUC.

Ensure that principle investigators include complete descriptions of all procedures within the protocols submitted to the IACUC. This provides the IACUC with all the information needed to approve protocols as required.

Correct from this time forward. This affected one animal.

### 2.31 (d) (2)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

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#### Prepared By:

DEBRA M SIME, D V M                      USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Apr-22-2009

#### Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Apr-22-2009



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A review of protocol #08-11-2 revealed that an amendment to the protocol adding an additional potentially painful procedure was approved by designated review. Further review of the IACUC meeting minutes and questioning of facility personnel revealed that the IACUC was not given the opportunity to request a full committee review of the amendment.

The facility failed to allow the IACUC a complete listing and description of a significant change to a protocol the opportunity for full IACUC committee review as required by regulation. This failure allowed for the potential for animals to be used inappropriately in research.

Ensure all protocols and significant changes to protocols are offered the opportunity for full IACUC committee review.

Correct from this time forward. This affected one animal.

Inspection and exit interview conducted with Director of Animal Care and Director of Preclinical Research.

End of report.

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**Prepared By:**

DEBRA M SIME, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1072

Apr-22-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Apr-22-2009



## Inspection Report

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THE INTEGRA GROUP

Customer ID: **36177**

Certificate: **41-R-0075**

Site: 001

INTEGRA RESEARCH FACILITY

4129 85TH AVENUE NORTH

Type: ROUTINE INSPECTION

BROOKLYN PARK, MN 55443

Date: Aug-08-2008

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No noncompliances identified on this inspection.

Inspection conducted with Operations Manager Comparative Medicine and Director of Preclinical Research.

Exit interview conducted with Operations Manager Comparative Medicine and Director of Preclinical Research and Vice President of Preclinical Research.

End of report.

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**Prepared By:**

DEBRA M SIME, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1072

Aug-08-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-08-2008



## Inspection Report

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THE INTEGRA GROUP

Customer ID: **36177**

Certificate: **41-R-0075**

Site: 002

THE INTEGRA GROUP

4129 85TH AVENUE NORTH

Type: ROUTINE INSPECTION

BROOKLYN PARK, MN 55443

Date: Jun-22-2010

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No non-compliant items identified during this inspection.

Inspection and exit briefing conducted with Farm Owner.

End of report.

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**Prepared By:**

DEBRA M SIME, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1072

Jun-29-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Jun-29-2010