

U. S. DEPARTMENT OF ENERGY  
OFFICE OF SCIENCE -- CHICAGO OFFICE

NATIONAL ENVIRONMENTAL POLICY ACT (NEPA)  
ENVIRONMENTAL EVALUATION NOTIFICATION FORM

To be completed by "financial assistance award" organization receiving Federal funding. For assistance (including a point of contact), see "Instructions for Preparing SC-CH F-560, Environmental Evaluation Notification Form".

Solicitation/Award No. (if applicable): DE-SC0005752

Organization Name: University of North Dakota

Title of Proposed Project/Research: Avian Diagnostic and Therapeutic Antibodies to Viral Emerging Pathogens

Total DOE Funding/Total Project Funding: \$2,916,000

I. Project Description (use additional pages as necessary):

A. Proposed Project/Action (delineate Federally funded/Non-Federally funded portions)

The proposed research is designed to rapidly advance the diagnostic evaluation of avian antibodies to viral strains and test their efficacy against West Nile Virus as therapeutic antibodies in animal studies and pre-clinical studies. WNV-specific goose antibodies will be produced under SPF conditions to be constructed within an existing barn on Schiltz Farms (see below; continuation on pg. 5). Upon validation of efficacy, UND will work with partners to quickly advance therapeutic antibodies through pre-clinical studies. This overall strategy offers a faster development time, rapid scalability, broader protection, and higher survival rates than those traditionally used.

(Continued on pg. 5)

B. Would the project proceed without Federal funding?

Yes  No

If "yes", describe the impact to the scope:

II. Description of Affected Environment:

Goose anti-WNV antibodies will be produced with vaccine stock WNV in geese held in an SPF area of a goose barn utilizing positive pressure and HEPA filtration (to be constructed within an existing barn). The vaccine preps are certified to contain only killed virus and the geese will be tested to insure that they are SPF prior to inclusion in these studies. (Avian BioTech, Inc./Schiltz Farms North)

Characterizations of the WNV-specific goose antibodies and assay development will be conducted in BSL-2 laboratories at SMHS and UNDRF by laboratory staff and graduate students trained in biosafety, although there will not be any infectious agents present in the antibody preparation. (UND SMHS and Avianax/UNDRF)

Pre-clinical investigation, including efficacy studies, will be performed at contract BSL-3 laboratories. (Tulane University)

~~which only requires a Level BSL-2 Lab~~

III. Preliminary Questions:

- A. Is the DOE-funded work *entirely* a "paper study"? Yes  No

*If "Yes", ensure that the description in Section I reflects this and go directly to Section V.*

- B. Will the work to be performed take place *entirely* in existing buildings? Yes  No

*And NOT:*

- |    |  |   |  |
|----|--|---|--|
| 1. | Threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health?  | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| 2. | Require the siting, construction or major expansion of waste treatment, storage, or disposal facilities?   | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| 3. | Disturb hazardous substances, pollutants, or contaminants preexisting in the environment?  | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| 4. | Adversely affect environmentally-sensitive resources identified in Section IV.A.?  | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| 5. | Be connected to another existing/proposed activity that could potentially create a cumulatively significant impact?  | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            |
| 6. | Have an inherent <i>possibility</i> for high consequence impacts to human health or the environment (e.g., Biosafety Level 3-4 laboratories, activities involving high levels of radiation)? | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> |

*If "Yes" to Question III.B. and ALL six subsequent questions, ensure the descriptions in Sections I and II reflect this and go directly to Section V.*

IV. Potential Environmental Effects:

**Attach/insert an explanation for each "Yes" response.**

- A. Sensitive Resources: Will the proposed action result in changes and/or disturbances to any of the following resources?

- |     |  | Yes                      | No                                  |
|-----|--|--------------------------|-------------------------------------|
| 1.  | Threatened/Endangered Species and/or Critical Habitats                         | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 2.  | Other Protected Species (e.g., Burros, Migratory Birds)                        | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 3.  | Sensitive Environments (e.g., Tundra/Coral Reefs/Rain Forests)                 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 4.  | Archaeological/Historic Resources  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.  | Important Farmland   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.  | Non-Attainment Areas for Ambient Air Quality Standards                         | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.  | Class I Air Quality Control Region   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.  | Special Sources of Groundwater (e.g. Sole Source Aquifer)                      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 9.  | Navigable Air Space  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 10. | Coastal Zones  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 11. | Areas with Special National Designation (e.g. National Forests, Parks, Trails) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 12. | Floodplains and Wetlands   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

- B. Regulated Substances/Activities: Will the proposed action involve any of the following regulated items or activities?

- |     |   | Yes                      | No                                  |
|-----|---|--------------------------|-------------------------------------|
| 13. | Natural Resource Damage Assessments   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 14. | Exotic Organisms  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 15. | Noxious Weeds   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 16. | Clearing or Excavation (indicate if greater than one acre)                              | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17. | Dredge or Fill (under Clean Water Act, Section 404, indicate if greater than ten acres) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

B. Regulated Substances/Activities: Will the proposed action involve any of the following regulated items or activities? (continued)

	Yes	No
18. Noise (in excess of regulations)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
19. Asbestos Removal	<input type="checkbox"/>	<input checked="" type="checkbox"/>
20. PCB's	<input type="checkbox"/>	<input checked="" type="checkbox"/>
21. Import, Manufacture, or Processing of Toxic Substances	<input type="checkbox"/>	<input checked="" type="checkbox"/>
22. Chemical Storage/Use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
23. Pesticide Use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
24. Hazardous, Toxic, or Criteria Pollutant Air Emissions	<input type="checkbox"/>	<input checked="" type="checkbox"/>
25. Liquid Effluents	<input type="checkbox"/>	<input checked="" type="checkbox"/>
26. Underground Injection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
27. Hazardous Waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>
28. Underground Storage Tanks	<input type="checkbox"/>	<input checked="" type="checkbox"/>
29. Radioactive Mixed Waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>
30. Radioactive Waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>
31. Radiation Exposure	<input type="checkbox"/>	<input checked="" type="checkbox"/>
32. Surface Water Protection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
33. Pollution Prevention Act	<input type="checkbox"/>	<input checked="" type="checkbox"/>
34. Ozone Depleting Substances	<input type="checkbox"/>	<input checked="" type="checkbox"/>
35. Off-Road Vehicles	<input type="checkbox"/>	<input checked="" type="checkbox"/>
36. Biosafety Level 3-4 Laboratory	<input checked="" type="checkbox"/>	<input type="checkbox"/>


C. Other Relevant Information: Will the proposed action involve the following?

	Yes	No
37. Potential Violation of Environment, Safety, or Health Regulations/Permits	<input type="checkbox"/>	<input checked="" type="checkbox"/>
38. Siting/Construction/Major Modification of Waste Recovery, or Waste Treatment, Storage, or Disposal Facilities	<input type="checkbox"/>	<input checked="" type="checkbox"/>
39. Disturbance of Pre-existing Contamination	<input type="checkbox"/>	<input checked="" type="checkbox"/>
40. New or Modified Federal/State Permits	<input type="checkbox"/>	<input checked="" type="checkbox"/>
41. Public Controversy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
42. Environmental Justice	<input type="checkbox"/>	<input checked="" type="checkbox"/>
43. Action/Involvement of Another Federal Agency (e.g. license, funding, approval)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
44. Action of a State Agency in a State with NEPA-type law. (Does the State Environmental Quality Review Act apply?)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
45. Public Utilities/Services	<input type="checkbox"/>	<input checked="" type="checkbox"/>
46. Depletion of a Non-Renewable Resource	<input type="checkbox"/>	<input checked="" type="checkbox"/>
47. Extraordinary Circumstances	<input type="checkbox"/>	<input checked="" type="checkbox"/>
48. Connected Actions	<input type="checkbox"/>	<input checked="" type="checkbox"/>
49. Exclusively Bench-top Research	<input type="checkbox"/>	<input checked="" type="checkbox"/>
50. Only a Laboratory Setting	<input type="checkbox"/>	<input checked="" type="checkbox"/>

V. Financial Assistance Award Organization Concurrence:

Barry Milavetz, Ph.D.; Assoc. Vice President for Research and Economic


A. Organization Official (Name and Title): Development

Signature:  Date: 02-22-2011

e-mail: barrymilavetz@mail.und.nodak.edu Phone: 701-777-4280

David S. Bradley, Ph.D.; Chair/Assoc. Prof; Microbiology/Immunology;

B. Optional Concurrence (Name and Title): UND SMHS (Project PI)

Signature:  Date: 02-22-2011

e-mail: david.s.bradley@med.und.edu Phone: 701-777-2610

Remainder to be completed by SC-CH

VI. SC-CH Concurrence/Recommendation/Determination:

A. SC-CH Office of Acquisition and Assistance or Office of Safety, Technical & Infrastructure Services:

Project Director or Contract Specialist (Name and Title): JILL JONKOUSKI

Signature: [Signature] Date: 3-16-11

B. SC-CH NEPA Team Review:

Is the project/activity appropriate for a determination or a recommendation to the Head of the Field Organization by the NEPA Compliance Officer (NCO) under Subpart D of the DOE NEPA Regulations?

Yes  No  B3.12 & B3.6

Specific class(es) of action from Appendices A-D to Subpart D (10 CFR 1021):

Name and Title: JAMES OPZEDK

Signature: [Signature] Date: 3-21-11

C. SC-CH Counsel (if necessary):

Name and Title: MICHELLE MCKOWN

Signature: [Signature] Date: 3-21-11

D. SC-CH NEPA Compliance Officer:

The preceding pages are a record of documentation required under DOE Final NEPA Regulation, 10 CFR 1021.400.

- Action may be categorically excluded from further NEPA review. I have determined that the proposed action meets the requirements for Categorical Exclusion referenced above.
- Action requires approval by Head of the Field Organization. Recommend preparation of an Environmental Assessment.
- Action requires approval by Head of the Field Organization or a Secretarial Officer. Recommend preparation of an Environmental Impact Statement.

Comments/Limitations if necessary: The categorical exclusion is subject to the limitations in the attached note.

Signature: [Signature] Date: 3/21/2011

Peter R. Siebach  
SC-CH NEPA Compliance Officer

## Siebach, Peter

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**From:** Schmidt, David [david.schmidt@research.und.edu]  
**Sent:** Thursday, March 17, 2011 1:50 PM  
**To:** Jonkouski, Jill; Siebach, Peter  
**Cc:** Keeley, Kim Lorraine; Bradley, David  
**Subject:** DOE questions

Jill and Peter,

I am writing to confirm the work at UND will be no higher than BSL II level. We will come back to DOE with additional information concerning any BSL III work.

The information concerning the Barn is as follows:

It must be clarified that NO infectious agent will be introduced to the farm in this project. Geese will be immunized with either killed virus (USDA certified killed vaccine preparations) or purified proteins. Therefore, there will not be any biohazard introduced in the farm setting. The geese would be producing antibodies, regardless of the immunization, the immunization will simply direct the specificity of the antibodies produced. Geese included in these studies will also be screened to ensure that they are free of indigenous infections.

The carcasses of geese utilized in these studies will be composed in accordance with State of South Dakota DNR regulations.

The HEPA filters will be utilized to filter incoming air, i.e. ambient air, to ensure a "clean" facility, and thus, will not contain any biohazard. However, when the HEPA filters are changed, the used filters will be double bagged, autoclaved in the REAC-1 facility, and disposed of in the trash.

All sharps will be collected in a commercially obtained "Sharps Receptacle". When full the sharps box will be autoclaved in the REAC-1 facility, and disposed of with the autoclaved waste.

If you have any other questions or need additional information, please contact me.

Dave

David O. Schmidt, CPA, CRA  
Assistant Vice President for Research  
& Economic Development  
University of North Dakota  
264 Centennial Drive, Stop 7306  
Twamley Hall, Room 100  
Grand Forks, ND 58202-7306

Phone: 701-777-2505

Fax: 701-777-2504

E-Mail: [david.schmidt@research.und.edu](mailto:david.schmidt@research.und.edu)

## Siebach, Peter

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**From:** McKown, Michelle  
**Sent:** Thursday, March 17, 2011 4:11 PM  
**To:** Siebach, Peter  
**Subject:** Regarding Conference Call yesterday on Avian Research grant

Pete,

Regarding your request for information provided by the grantee yesterday regarding the research activities occurring in ND, the grantee disclosed that the research at U ND would occur with or without the research activities at Tulane University. The ND research has independent utility in that they are researching the purification/processes related to purification of the goose antibodies to West Nile virus.

Please let me know if you have any further requests or need more clarification.

Thanks!

*Michelle R. McKown*  
Attorney Advisor  
United States Department of Energy  
9800 S. Cass Avenue  
Argonne, IL 60439  
Phone: 630-252-5057  
Fax: 630-252-2183

Note

Date: March 21, 2011

From:  Peter Siebach, NEPA Compliance Officer, Chicago Office

Subject: Grant No. DE-SC0005752 - Avian Diagnostic and Therapeutic Antibodies,  
University of North Dakota and Tulane University

The categorical exclusion for the subject action applies only to:

1. Work at the University of North Dakota disclosed in the approved Environmental Evaluation Notification Form.
2. Work classified as less than biosafety level 3

Work proposed Tulane University will be considered in a separate NEPA determination.

**Continuation from I. Projection Description, A. Proposed Project/Action: (pg 1)**

A "Specific Pathogen Free" (SPF) goose holding area will be constructed by renovation of an existing barn on Schiltz Farms. Mr. Ted Gilbert will provide consultation for this renovation, based on his 10- plus years experience in the Pharmaceutical/Biotech/Food industries and as a Consultant and Project Manager for regulated activities with both the FDA and USDA. The construct facility will provide a "clean" facility for the holding of the experimental geese. It will include a traffic flow plan to ensure that containments are not carried into the SPF area; HEPA filtration of incoming air supply; and positive pressure. The renovated area is by design clean and does not pose any health hazards. The purpose of this holding area is to ensure that the geese being utilized for antibody production do not become infected by other microbial agents. There will not be any new construction to achieve this area as it is completely contained within the footprint of an existing barn.

The geese being held with in the SPF holding area will be tested prior to moving them into this area to ensure that they do not carry known avian pathogens. Thus, the birds included in this study will not pose any biohazard at their inclusion into these studies. The geese will then be immunized with killed WNV, vaccine stock certified as killed, thus also not presenting any potential health hazards.

**Section III.B.6 and IV.36**

*In vitro* and *in vivo* preclinical studies will be conducted with the purified WNV-specific goose antibodies under contract with the laboratory of Dr. Thomas Voss, Tulane University. Dr. Voss' laboratory is well established in BSL-3 studies with WNV and other BSL-3 microorganisms, including his personal research and other contract research including for the NIH-NIAID. These studies will be under the regulatory oversight of Tulane University's Institutional Biosafety Committee, Tulane Health Sciences Center, 1440 Canal Street, Suite 830 TW-5, New Orleans, LA 70112 (TEL: 504-988-0300; FAX: 504-988-0370; E-mail [ibc@tulane.edu](mailto:ibc@tulane.edu)) and Institutional Animal Care & Use Committee, 1430 Tulane Ave. TB 23, New Orleans, La. 70112 (TEL: 504-988-6868; FAX: 504-988-1445; E-mail [iacuc@tulane.edu](mailto:iacuc@tulane.edu)). SOP will be submitted and approved for these studies by Dr. Voss prior to their initiation.