

**CALIFORNIA POLYTECHNIC STATE UNIVERSITY
SAN LUIS OBISPO, CA**

**ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals**

I, Susan Opava-Stitzer, Dean of Research and Graduate Programs, as named Institutional Official for animal care and use at California Polytechnic State University, San Luis Obispo (Cal Poly), hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live vertebrate animals supported by the Public Health Service (PHS) and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or -supported activity by this Institution.

"Institution" includes the following branches and major components of Cal Poly: all recognized academic departments and units within the colleges at California Polytechnic State University, San Luis Obispo, including the College of Agriculture Food and Environmental Sciences, College of Architecture and Environmental Design, Orfalea College of Business, College of Education, College of Engineering, College of Liberal Arts, and College of Science and Mathematics.

II. INSTITUTIONAL COMMITMENT

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

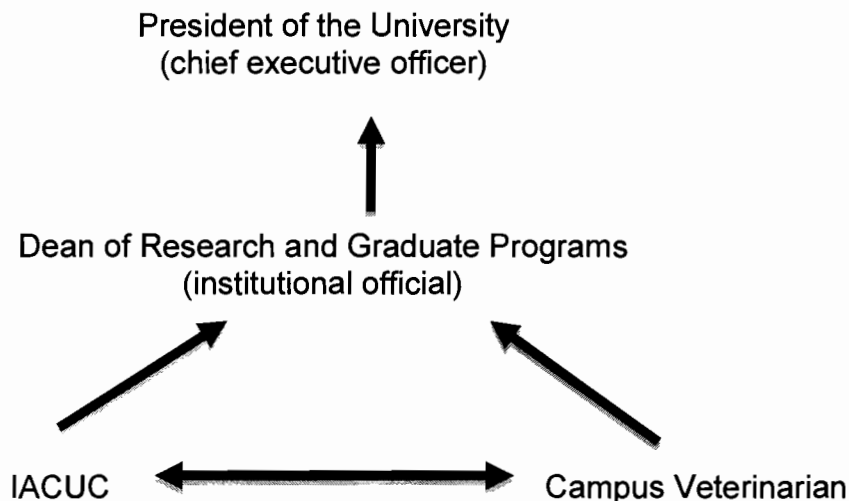
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:

Cal Poly's institutional animal care and use committee (IACUC) directly oversees and administers all regulated animal use on campus, reviews the institution's policies and compliance with Federal regulations, and its adherence to the guidelines set forth in the "Guide". All actions of the IACUC include the participation of the campus veterinarian who has direct authority in all animal care matters. The IACUC and campus veterinarian report directly to the Institutional Official (IO), the Dean of Research and Graduate Programs. This includes all decisions on animal care and use protocols, inspections, reports, and concerns regarding animal use at the institution. The IO reports to the President of the University, the chief executive officer, who is responsible for overall administrative responsibility and implementation of the institution's program for care and use of animals to ensure that all humane, ethical and legal requirements are met. The diagram below summarizes the reporting channels:



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Dale Smith

Qualifications:

- Degrees: Doctor of Veterinary Medicine (UCDavis)
- Training and/or experience in laboratory animal medicine: Dr. Smith is the campus veterinarian and a professor in the Animal Science Department

and has overseen the campus veterinary clinic for over thirty years and regularly attends laboratory animal care professional meetings.

- Authority: Dr. Smith has direct program authority and responsibility for the Institution's animal care and use program.

Time Contributed to Program: Dr. Smith is a full-time faculty member, and the proportion of his time dedicated to the animal care and use program may be as little as 5% for general oversight of animal use, up to 50% depending on need.

[NOTE: If there is more than one veterinarian associated with the program, please provide the information requested below for each. If only one veterinarian is associated with the program, describe provisions in place for a back-up veterinarian to ensure adequate veterinary care of research animals should that veterinarian not be available.]

Name: Matthew Burd

Qualifications:

- Degrees: Doctor of Veterinary Medicine (UC Davis)
- Training and/or experience in laboratory animal medicine: Dr. Burd is a licensed veterinarian with extensive experience in small and large animal surgery.

Responsibilities: Dr. Burd is a professor in the Animal Science Department

Time Contributed to Program: Dr. Burd is a full-time faculty member, and is available to serve as a backup veterinarian when needed.

Name: Jaymie Noland

Qualifications:

- Degrees: Doctor of Veterinary Medicine (Colorado State University)
- Training and/or experience in laboratory animal medicine: Dr. Noland is a licensed veterinarian with extensive experience in small and large animal surgery and internal medicine.

Responsibilities: Dr. Noland is a professor in the Animal Science Department

Time Contributed to Program: Dr. Noland is a full-time faculty member, and is available to serve as a backup veterinarian when needed.

Additional provisions for backup veterinary care, particularly in the cases where uncommon species are utilized or specialized expertise is called for, include the requirement of each investigator to establish a backup veterinarian from off campus that is qualified for the project at hand and has been consulted and agrees to participate as a backup veterinarian. Their credentials and contact information is included on all protocols for animal use.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified

through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC meets twice annually for the specific task of reviewing the institution's program for humane care and use of animals. The meeting is led by the IACUC chair, and follows the Sample Semiannual Program Review Checklist provided by OLAW. The committee reviews each point and establishes whether it is adequately addressed or discusses the reasons for suspecting that it is not adequately addressed, and whether this inadequacy constitutes a minor or severe deviation. In cases where the point on the sample checklist does not apply to the program, that is discussed and so noted.

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

The semiannual facilities inspections are conducted as a group tour led by the campus veterinarian and/or IACUC chair, and follow the Sample Semiannual Review Checklist provided by OLAW. The committee reviews each point and establishes whether it is adequately addressed or discusses the reasons for concluding that it is not adequately addressed, and whether this inadequacy constitutes a minor or severe deviation. In cases where the point on the sample checklist does not apply to the facilities, that is discussed and so noted.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

Overall program review and inspection of facilities is performed semi-annually and the full reviews are maintained by the IACUC, and submitted to the IO. Any deficiencies or departures from the "Guide" are identified in the report and distinguished as either major or minor, and suggestions for remedies are also included. These semi-annual reports include any deficiencies noted and a recommended plan and schedule for correction.

Annual reports are also developed by the committee are constructed as a summary of the major activities of the IACUC over the year (number of meetings, number of protocols reviewed, approved and not approved) and any deficiencies identified during the semiannual program and facilities reviews, as well as any suggestions for improvement of the program or facilities that the IACUC has identified during its activities. This report is compiled by the IACUC chair and circulated to all IACUC members for input and revision. Once revisions are incorporated, the final report is again circulated to the entire committee for final approval and signature and sent to the IO. The IO reviews the report and forwards it to the Chief Executive Officer.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

At Cal Poly, all concerns involving animal care and use are to be reported directly to the IO, the Dean of Research and Graduate Programs. Concerns may also be reported directly to members of the IACUC, who will then report them directly to the IO. If the IO or the IACUC are suspected of a conflict of interest, the reports are to be made directly to the Vice President for Academic Affairs. Review of such allegations is made initially by the campus veterinarian and IACUC chair, and then reported in full to the IO and the committee. Action plans are developed by discussion among the IACUC members and the IO.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Recommendations relating to animal care, whether programmatic, facility-, or training-related, are developed by committee discussion, put in writing by the IACUC chair, and reported to the IO in the semi-annual reports. If more immediate action is needed, recommendations are developed by committee discussion and reported to the IO by the IACUC chair on an as-needed basis.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

Projects involving animal subjects may not begin until approved by the committee, regardless of the type of project or its source of funding, including those cases where no reimbursement for such activities is involved. No changes in the project plan may be made without prior approval of the IACUC. Investigators will bring to the committee's attention any emergent problems or

proposed procedural changes that may affect the protocol conditions and/or approval status of the project. All long-term projects involving animal subjects, including classroom instructional use, must be reviewed and reapproved by the IACUC every three years.

Investigators must submit a Protocol for Animal Use to the chair of the IACUC describing proposed work involving studies with vertebrate animal subjects, regardless of funding source or purpose (research, testing or education), at least sixty days before the animal use is planned to commence. Protocols are submitted by email to the IACUC chair, who forwards them by email to the IACUC. The committee is given one week to call for full-committee review. If full review is requested by any member, a meeting is convened and the protocol is discussed and voted upon by a quorum of the IACUC. If no member requests full-committee review, the chair designates the review to one or more IACUC members based on their appropriate qualifications relative to the protocol. The designated reviewer

No committee member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest, except to provide information as requested by the IACUC, nor may a member who has a conflict of interest contribute to the constitution of a quorum.

Whether in full-committee review or designated review, the IACUC or designated reviewer(s) shall evaluate all components related to the care and use of animals to determine that the proposed research and/or teaching protocols will be conducted in accordance with institutional policies. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the PHS Policy and the Animal Welfare Act insofar as it applies to the research project, and that the research protocol is consistent with the "Guide", unless an acceptable justification for a departure is presented in writing.

Review of animal use protocols by the IACUC results in either approval, tabling and return to the investigator for modification/clarification and resubmission, or disapproval. In some cases during full-committee review, the IACUC will vote to approve the protocol contingent on minor administrative modifications (such as missing contact information, misspelled words, disposal procedure modifications, etc.) required to secure approval, inclusion of which is verified by the IACUC chair prior to granting official approval. Review of animal use protocols by designated reviewer(s) results in either approval, return to the investigator for modification/clarification and resubmission, or referral of the protocol for review by the full committee. If the protocol is returned to the investigator for modification/clarification and resubmission, the resubmitted protocol is reviewed again by the same person or persons who conducted the initial review (i.e. full committee or designated reviewer(s)) for determination of satisfactory revision. Once revisions are deemed satisfactory, approval is granted.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Written notification by the investigator to the IACUC for approval is required before significant changes can be made to an approved protocol. Evaluation of amendments to protocols originally subjected to full-committee review are handled in the same way as new protocols (described under part III.D.6.) and may be subjected to designated review if no committee member requests full review. Amendment applications for protocols originally subjected to designated review for which no member calls for full-committee review are assigned to the member(s) that originally conducted the designated review.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC chair notifies investigators regarding proposals approved following the IACUC meeting and a copy of that correspondence is sent to the IO. If tabled, or disapproved, the investigators are notified by the chair of the IACUC of the committee's action on their proposal and reasons for the decision made. In these cases the investigator must submit a revised protocol prior to subsequent review. Tabled and disapproved proposals are scheduled for reconsideration by the IACUC following a response from the investigator. Review of resubmitted protocols that were tabled or disapproved are conducted in the same manner as new protocol submittals.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC regularly communicates with researchers and is aware of on going protocol activity prior to the three-year review. All investigators are notified that they must inform the IACUC of any changes in their protocol which might affect the care and use of laboratory animals. All protocols expire after three years, and any continuing activity must be reviewed again by the IACUC for extension to an additional three years. The review process for renewal of protocols is the same as that for newly submitted protocols as is described above in section

III.D.6. If the renewal of a protocol is not initiated by the investigator after the three year expiration, the IACUC contacts the investigator to verify that the project is completed and establish the actual number of animals used in the project.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide and/or the Institution's Animal Welfare Assurance. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present except in cases where the immediate welfare of animals is in jeopardy, as determined by the campus veterinarian. In such cases, the campus veterinarian has authority to suspend immediate activities and call a meeting of the IACUC to discuss the activities in question. The IO, in consultation with the IACUC will review the reason(s) for suspension of activities and determine the appropriate corrective action. Additional review may occur if warranted as outlined in the institution's "Policies and Procedures for the Handling of Allegations of Scientific Fraud and Serious Misconduct." Any suspended activity will be reported with explanation to OLAW.

The Institutional Official will report suspensions and other significant non-compliance events in accord with Notice Number: NOT-OD-05-034, *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*. Reports will be directed to:

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

E. Cal Poly's Environmental Health and Safety Office oversees the Cal Poly Animal Handler Occupational Health and Safety Program (<http://www.afd.calpoly.edu/ehs/>). The campus Environmental Health and Safety Manager is responsible for risk management on campus, including this program. As a member of the IACUC, his participation in the review of all protocols ensures compliance with health and safety regulations and training requirements.

All faculty, staff and students who handle animals are subject to the requirements of the Cal Poly Animal Handler Occupational Health and Safety Program. They are made aware of the program through information included in the IACUC protocol submission materials, which are posted on the IACUC website. As part of the IACUC protocol submission process, each individual who will be involved in the handling of animals is required to complete Part 1 of the Animal Contact Review and Initial Health Surveillance Questionnaire (ACRIHSQ; see Attachment 1). It is the responsibility of the primary investigator to ensure that all personnel involved in the project, including students, complete this form. On the basis of the information provided in Part I of the ACRIHSQ the IACUC will determine which individuals should be enrolled in the Medical Surveillance Program. Individuals so designated will be required to complete Part II of the ACRIHSQ. This information is confidential and will be sent directly by the enrollee to the University's contract medical provider for evaluation and appropriate action regarding needed immunizations, special precautions, and surveillance.

The Cal Poly Animal Handler Occupational Health and Safety Program covers the following:

- Preventive medicine
- Allergies
- Immunizations
- Animal-related illnesses, injuries and unsafe conditions
- Personnel hygiene and protective equipment
- Serum banking
- Practices, safety equipment and facilities (animal biosafety levels)
- Species-specific precautions and information.

The Cal Poly Animal Handler Occupational Health and Safety Program requires that all individuals who will be working with animals receive training on the potential health and safety issues related to the care and use of various animal species. This training will be provided by the Environmental Health and Safety Office through training materials prepared by Cal Poly or materials available online from other sources. All training materials will be available via the campus' new online learning management and training system, LearnerWeb. All students, faculty, and staff have access to this system, and appropriate course enrollments will be made by the Environmental Health & Safety Office. Specific safety practices, safety equipment, and personal protective equipment (PPE) appropriate for each animal facility is available from the manager of that facility and provided to each new trainee. PPE supported by the Program includes safety glasses, chemical splash goggles, labcoats, impermeable clothing/aprons, gloves, face shields, protective footwear, hardhats, air purifying respirators, self contained breathing apparatus. Training, consultation and fit tests are provided by the Environmental Health and Safety Office.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Each investigator must either provide documentation of prior training in animal care at another institution or complete the training modules adopted by Cal Poly and available through the IACUC to any interested party. It is the responsibility of each investigator to ensure that personnel involved in the project are trained in animal care and handling and acknowledgement of this responsibility is documented by the investigator on the Protocol for Animal Use form. Cal Poly has adopted online animal care training modules developed by the University of Arizona IACUC (<http://www.iacuc.arizona.edu/training/>). These modules are currently available in both electronic and downloadable formats. These include "Laws and Regulations," "Introduction to Animal Hazards," "Zoonotic Diseases," "Surgery and Anesthesia," and many species-specific modules. The IACUC maintains records of the online training modules completed by any individual, and provides documentation of that training to the individual. All members of the IACUC are also provided access to these training modules, and are provided with any other materials required for appropriate background needed for IACUC service. These include the AVMA Report on Euthanasia, the Guide, the PHS Policy, the ARENA/OLAW IACUC Guidebook and a copy of the approved Assurance. Copies of the PHS Policy and pertinent reference materials are available on the OLAW website under resources at: http://grants.nih.gov/grants/olaw/request_publications.htm and the approved Assurance is available through the IACUC chair.

When requested by the investigator or other personnel working on the project, the IACUC will provide additional assistance or instruction in the humane care and handling of laboratory animals. In all cases, the IACUC will ensure that any investigator who cannot document necessary training and experience to handle laboratory animals or to conduct animal experiments in accordance with the Guide will receive appropriate training and demonstrate their credentials to a panel including the campus veterinarian and at least one other IACUC member. Personnel that provide any training will be experienced in laboratory animal care (i.e., the campus veterinarian or other similarly qualified individuals).

The campus veterinarian is available to consult with faculty on the proper use of anesthesia, analgesics, and methods of euthanasia. The training modules currently in use include sections on minimizing animal pain and distress, as well as methods to minimize the number of animals used while still obtaining valid results, including alternatives to alive animal models. In addition, the IACUC

offers assistance to any investigator in the further exploration of these issues, and these items are specifically assessed during protocol review.

No species covered under the Animal Welfare Act is currently used for research at Cal Poly.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. RECORDKEEPING REQUIREMENTS

- A. This Institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official.
 5. Records of accrediting body determinations.

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. This Institution's reporting period is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official.

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the "Guide."
3. Any suspension of an activity by the IACUC.

C. Reports filed under sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Susan Opava-Stitzer, Ph.D.

Title: Dean of Research and Graduate Programs

Name of Institution: California Polytechnic State University

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E-mail: sopava@calpoly.edu

Signature: 

Date: 6/29/09

B. PHS Approving Official

Name:

Title:

Address:

Phone:

Fax:

E-mail:

Signature:

Date:

C. Effective Date of Assurance:

D. Expiration Date of Assurance: