

purposes of this Policy, a clinical trial is defined as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”⁷

Effective Date. This Policy is effective for:

- Competing grant applications that include clinical trials and are submitted to the NIH for the [date to be determined] receipt date and subsequent receipt dates;
- Proposals for contracts that include clinical trials and are submitted to the NIH on or after [date to be determined]; and
- NIH intramural research projects that include clinical trials for which Institutional Review Board review is initiated after [date to be determined].

Responsibilities. As set forth in the terms and conditions of grant and contract awards, all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by NIH, who have committed to NIH that they will comply with NIH policies, are expected to ensure that their NIH-funded clinical trials are registered and summary results, including adverse event information, are submitted to ClinicalTrials.gov in

⁷ Several terms within the NIH definition of clinical trial definition mean are defined as follows. “Research” and “human subject” are defined in the Common Rule at 45 CFR 46.102(d) and 45 CFR 46.102(f), respectively. “Prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. An “intervention” is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies. A “health-related biomedical or behavioral outcome” is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life. See <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>

accord with the timelines that will be set forth at ClinicalTrials.gov. Generally, this means registration of the clinical trial not later than 21 days after enrollment of the first participant and submission of summary results information not later than one year after the completion date. “Completion date” is defined to be the date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. It will be possible to delay results submission for up to two years beyond the initial deadline with a certification that regulatory approval of the product is being sought. Clinical trials covered by the policy will be expected to submit the same type of registration and results data and in the same timeframes as the trials subject to FDAAA. The specific registration and results information to be submitted will be made available at the ClinicalTrials.gov site.

Institutions and investigators should submit information directly to ClinicalTrials.gov. If the trial is subject to FDAAA, *i.e.*, section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), submissions must be made by the Responsible Party, as defined at 42 U.S.C. 282(j)(1)(A)(ix). If an NIH-funded clinical trial is also subject to FDAAA, it needs to have only one entry in ClinicalTrials.gov that contains its registration and results information. Investigators and funding recipients are expected to cooperate with NLM to address any data curation or quality control issues to facilitate timely posting.

In general, NIH expects to make clinical trial registration and results information publicly available through ClinicalTrials.gov within 30 days after receipt by ClinicalTrials.gov.⁸ For NIH-funded trials that are subject to section 402(j) of the Public Health Services Act (42 U.S.C. 282(j)), submitted information will be posted in compliance with the relevant requirements of that section.

Failure to comply with the terms and conditions of NIH awards may provide a basis for enforcement actions, including termination, consistent with

⁸ For clinical trials funded through SBIRs, the timeframe for posting results will be consistent with the SBIR Policy Directive, which generally prohibits the agency from posting SBIR data for at least 4 years from completion of the study unless the awardee consents to an earlier release. See SBIR Policy Directive, Sections 8(b)(2) and (4).

45 CFR 74.62 and/or other authorities, as appropriate.⁹

Dated: January 8, 2015.

Lawrence Tabak,

Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

[AAK6006201 1565A2100DD
AOR303.999900]

National Environmental Policy Act: Implementing Procedures; Additions to Categorical Exclusions for Bureau of Indian Affairs (516 DM 10)

AGENCY: Department of the Interior.

ACTION: Notice of Final National Environmental Policy Act Implementing Procedures.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality regulations implementing NEPA, and Department of the Interior (Department) NEPA implementing regulations, the Bureau of Indian Affairs (BIA) in the Department is adding three categorical exclusions (CE) to the Departmental Manual 516 DM 10. The three proposed CEs pertain to timber harvesting on Indian lands.

DATES: *Effective Date:* The categorical exclusions are effective February 13, 2015.

ADDRESSES: To obtain a copy of the new categorical exclusions contact Mr. David Koch, Acting Chief Forester, Bureau of Indian Affairs, 1849 C Street, Washington, DC 20240; email: david.koch@bia.gov.

FOR FURTHER INFORMATION CONTACT: Mr. David Koch, Acting Chief Forester, (202) 208-4837.

SUPPLEMENTARY INFORMATION:

Background

Harvesting timber on Indian lands, as defined in 25 CFR 163.1, allows landowners to realize value from lands held in trust for them by the Federal Government or subject to restrictions against alienation. The National Indian Forest Resources Management Act, and its implementing regulations, require the Secretary, with the participation of the landowners, to undertake forest land management activities on Indian forest

⁹ When the final policy is issued, NIH will also provide more specific procedural guidance to facilitate implementation.

lands, including the approval of timber harvests. As a result of the need for Federal permits and contracts, such projects are Federal actions that require compliance with the NEPA. The BIA has typically conducted NEPA reviews of actions associated with timber harvesting by preparing Environmental Assessments (EA). The addition of CEs to cover these three categories of small actions will allow for a more efficient NEPA review because those EAs resulted in findings of no significant impacts which were substantiated over time. The three proposed CEs were developed based on CEs currently used by the United States Forest Service (FS), as described in FS regulations 36 CFR 220, and adopted by the Bureau of Land Management (BLM), as described the Departmental Manual, 516 DM 11. The BIA relied on the experience of the FS and BLM and applied its expertise to benchmark these CEs and determined these are appropriate to establish as BIA CEs.

Because these CEs have important implications for actions occurring on Indian lands, the BIA initiated consultation and requested comments from all federally recognized tribes. This consultation period began on July 23, 2014, and concluded on September 21, 2014. Public comments were also solicited through a notice placed in the **Federal Register** on November 14, 2014 [79 FR 68287].

Comments on the Proposal

The BIA received no comments from tribes, and no public comments.

Conclusion

The Department and the BIA determined that the actions defined in the CEs presented at the end of this notice normally do not individually or cumulatively have a significant effect on the human environment and, absent extraordinary circumstances, do not require preparation of an Environmental Assessment or an Environmental Impact Statement. This finding is based on the analysis of the application of similar CEs established and used by other Federal departments and agencies; and the professional judgment of BIA environmental and forestry personnel who conducted environmental reviews of similar actions that resulted in Findings of No Significant Impact.

Categorical Exclusions

The Department will add the following categorical exclusions to the Departmental Manual at 516 DM 10.5: H. Forestry.

(11) Harvesting live trees not to exceed 70 acres, requiring no more than

0.5 mile of temporary road construction. Such activities:

(a) Shall not include even-aged regeneration harvests or vegetation type conversions.

(b) May include incidental removal of trees for landings, skid trails, and road clearing.

(c) May include temporary roads which are defined as roads authorized by contract, permit, lease, other written authorization, or emergency operation not intended to be part of the BIA or Tribal transportation systems and not necessary for long-term resource management. Temporary roads shall be designed to standards appropriate for the intended uses, considering safety, cost of transportation, and impacts on land and resources; and

(d) Shall require the treatment of temporary roads constructed or used so as to permit the reestablishment by artificial or natural means, of vegetative cover on the roadway and areas where the vegetative cover was disturbed by the construction or use of the road, as necessary to minimize erosion from the disturbed area. Such treatment shall be designed to reestablish vegetative cover as soon as practicable, but at least within 10 years after the termination of the contract.

Examples include, but are not limited to:

(a) Removing individual trees for sawlogs, specialty products, or fuelwood.

(b) Commercial thinning of overstocked stands to achieve the desired stocking level to increase health and vigor.

(12) Salvaging dead or dying trees not to exceed 250 acres, requiring no more than 0.5 mile of temporary road construction. Such activities:

(a) May include incidental removal of live or dead trees for landings, skid trails, and road clearing.

(b) May include temporary roads which are defined as roads authorized by contract, permit, lease, other written authorization, or emergency operation not intended to be part of the BIA or Tribal transportation systems and not necessary for long-term resource management. Temporary roads shall be designed to standards appropriate for the intended uses, considering safety, cost of transportation, and impacts on land and resources; and

(c) Shall require the treatment of temporary roads constructed or used so as to permit the reestablishment, by artificial or natural means, of vegetative cover on the roadway and areas where the vegetative cover was disturbed by the construction or use of the road, as necessary to minimize erosion from the

disturbed area. Such treatment shall be designed to reestablish vegetative cover as soon as practicable, but at least within 10 years after the termination of the contract.

(d) For this CE, a dying tree is defined as a standing tree that has been severely damaged by forces such as fire, wind, ice, insects, or disease, such that in the judgment of an experienced forest professional or someone technically trained for the work, the tree is likely to die within a few years.

Examples include, but are not limited to:

(a) Harvesting a portion of a stand damaged by a wind or ice event.

(b) Harvesting fire damaged trees.

(13) Commercial and non-commercial sanitation harvest of trees to control insects or disease not to exceed 250 acres, requiring no more than 0.5 miles of temporary road construction. Such activities:

(a) May include removal of infested/infected trees and adjacent live uninfested/uninfected trees as determined necessary to control the spread of insects or disease; and

(b) May include incidental removal of live or dead trees for landings, skid trails, and road clearing.

(c) May include temporary roads which are defined as roads authorized by contract, permit, lease, other written authorization, or emergency operation not intended to be part of the BIA or tribal transportation systems and not necessary for long-term resource management. Temporary roads shall be designed to standards appropriate for the intended uses, considering safety, cost of transportation, and impacts on land and resources; and

(d) Shall require the treatment of temporary roads constructed or used so as to permit the reestablishment, by artificial or natural means, of vegetative cover on the roadway and areas where the vegetative cover was disturbed by the construction or use of the road, as necessary to minimize erosion from the disturbed area. Such treatment shall be designed to reestablish vegetative cover as soon as practicable, but at least within 10 years after the termination of the contract.

Examples include, but are not limited to:

(a) Felling and harvesting trees infested with mountain pine beetles and immediately adjacent uninfested trees to control expanding spot infestations (a buffer); and

(b) Removing or destroying trees infested or infected with a new exotic insect or disease, such as emerald ash borer, Asian longhorned beetle, or sudden oak death pathogen.

Dated: February 5, 2015.

Willie R. Taylor,

Director, Office of Environmental Policy and Compliance.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-ES-2014-N247;
FXES11130100000C4-156-FF01E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of 133 Species in Hawaii, Oregon, Idaho, and Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year status reviews for 133 species in Hawaii, Oregon, Idaho, and Washington under the Endangered Species Act of 1973, as amended (Act). A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any new information on these species that has become available since the last review.

DATES: To ensure consideration in our reviews, we are requesting submission of new information no later than April 14, 2015. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For the 130 species in Hawaii (see table below), submit information to: Deputy Field Supervisor—Programmatic, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Pacific Islands Fish and

Wildlife Office, 300 Ala Moana Blvd., Room 3-122, Box 50088, Honolulu, HI 96850.

For Bradshaw's desert-parsley and Howell's spectacular thelypody, submit information to: Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266.

Alternatively you may submit information on the Oregon species by email to: fw1or5yearreview@fws.gov.

For MacFarlane's four-o'clock, submit information to: Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Suite 368, Boise, ID 83709.

FOR FURTHER INFORMATION CONTACT:

Marie Bruegmann, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office (see **ADDRESSES**), 808-792-9400 (for species in Hawaii); Jeff Dillon, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 503-231-6179 (for Bradshaw's desert-parsley and Howell's spectacular thelypody); or Kim Garner, Idaho Fish and Wildlife Office, 208-378-5243 (for MacFarlane's four-o'clock). Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Why do we conduct 5-year reviews?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2) of the Act requires us to review each listed species' status at least once every 5 years to determine whether it should be

removed from the List; or be changed in status from endangered to threatened, or from threatened to endangered. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review.

What information do we consider in the review?

A 5-year review considers all new information available at the time of the review. In conducting these reviews, we consider the best scientific and commercial data that has become available since the listing determination or most recent status review, such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the Act); and

(E) Other new information, data, or corrections, including but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for these species.

What species are under review?

This notice announces our active review of the 133 species listed in the table below.

SPECIES FOR WHICH WE ARE INITIATING A 5-YEAR STATUS REVIEW

Common name	Scientific name	Status	Where listed	Final listing rule
ANIMALS				
Millerbird, Nihoa	<i>Acrocephalus familiaris kingi</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.
Wolf spider, Kauai cave	<i>Adelocosa anops</i>	Endangered	U.S.A. (HI)	65 FR 2348; 01/14/2000.
Duck, Laysan	<i>Anas laysanensis</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.
Pomace fly [unnamed]	<i>Drosophila musaphilia</i>	Endangered	U.S.A. (HI)	71 FR 26835; 05/09/2006.
Fly, Hawaiian picture-wing	<i>Drosophila sharpi</i>	Endangered	U.S.A. (HI)	75 FR 18960; 04/13/2010.
Newcomb's snail	<i>Erinna newcombi</i>	Threatened	U.S.A. (HI)	65 FR 4162; 01/26/2000.
Nukupu'u (honeycreeper)	<i>Hemignathus lucidus</i>	Endangered	U.S.A. (HI)	35 FR 16047; 10/13/1970.
'Akialoa, Kauai	<i>Hemignathus procerus</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.
Akekee	<i>Loxops caeruleirostris</i>	Endangered	U.S.A. (HI)	75 FR 18960; 04/13/2010.
'O'o, Kauai	<i>Moho braccatus</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.
Thrush, large Kauai	<i>Myadestes myadestinus</i>	Endangered	U.S.A. (HI)	35 FR 16047; 10/13/1970.
Thrush, small Kauai	<i>Myadestes palmeri</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.
'Akikiki	<i>Oreomystis bairdi</i>	Endangered	U.S.A. (HI)	75 FR 18960; 04/13/2010.
Amphipod, Kauai cave	<i>Spelaeorchestia koloana</i>	Endangered	U.S.A. (HI)	65 FR 2348; 01/14/2000.
Finch, Laysan	<i>Telespyza cantans</i>	Endangered	U.S.A. (HI)	32 FR 4001; 03/11/1967.