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Final Environmental Assessment
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Oocyte Growth Factor Vaccine Study

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BLM

1.0 Purpose and Need for Action

1.1 Introduction

This environmental assessment (EA) has been prepared to disclose and analyze the environmental impacts of a proposed Population Growth Suppression study that would test the contraceptive effects of an oocyte growth factor vaccine. The Bureau of Land Management (BLM), Nevada State Office (NSO) in cooperation with United States Department of Agriculture, Animal and Plant Health Inspection Services National Wildlife Research Center (NWRC) would conduct the research with previously-gathered wild horses that BLM has removed from the range and determined to be excess. *See* 16 U.S.C. § 1533(b).

This EA analyzes the potential impacts that could result with the implementation of either the Proposed Action or a No-Action alternative to the Proposed Action. BLM also considered other alternatives but has dismissed them from a more detailed analysis as they do not fulfill the purpose and need identified in the EA. Preparation of an EA assists the BLM authorized officer to determine whether to prepare an Environmental Impact Statement (EIS) if significant impacts could result, or a Finding of No Significant Impact (FONSI) if no significant impacts are expected.

1.2 Background

The Wild Free-Roaming Horses and Burros Act (WFRHBA) of 1971 directs BLM to "protect and manage wild free-roaming horses and burros as components of the public lands." 16 U.S.C. § 1333(a). BLM is required to manage the horses and burros in a manner that is "designed to achieve and maintain a thriving natural ecological balance on the public lands." *Id.* The Interior Board of Land Appeals defined the goal for managing wild horse (or burro) populations in a thriving natural ecological balance as follows: "As the court stated in Dahl vs. Clark, supra at 594, the 'benchmark test' for determining the suitable number of wild horses on the public range is 'thriving natural ecological balance.' In the words of the conference committee which adopted this standard: 'The goal of WH&B management should be to maintain a thriving ecological balance (TNEB) between WH&B populations, wildlife, livestock and vegetation, and to protect the range from the deterioration associated with overpopulation of wild horses and burros.'"

The WFRHBA states that BLM must "make determinations as to whether and where an overpopulation exists and whether action should be taken to remove excess animals." *Id.* § 1333(b)(1). To make that determination, BLM has established appropriate management levels (AML) for public lands. *Id.* If the number of wild horses and burros exceeds the AML and action is necessary to remove the animals, BLM must "immediately remove excess animals from the range to achieve" AML. *Id.* § (b)(2). While stating that BLM's management activities should be "at the minimal feasible level," the WFRHBA also mandates that BLM determine whether AML can be achieved "by the removal or destruction of excess animals, or other options (such as sterilization, or natural controls on population levels)." *Id.*; *id.* § 1333(a).

Wild horses and burros tend to have exceptionally high reproductive and survival rates. BLM has determined that the high end of AML for wild horses and burros on the public range across ten western states is 26,690. However, as of March 1, 2019, there was an estimated 88,090 wild horses and burros on the range, 47,468 of which are in the State of Nevada. Therefore, the population on the range exceeds AML by more than 61,400 animals in total – with almost half of those animals in Nevada. In addition to those animals on the range, as of January 17, 2020, there are over 49,500 wild horses and burros that BLM houses in short- and long-term care facilities. BLM gathered and removed these animals from the range after it determined that an overpopulation existed in areas on the range. There is limited funding

and space available for the care of additional animals in short- and long-term care facilities, and insufficient adoption demand for the excess horses removed from the range.

BLM has attempted to address both the high population growth rate of wild horses and burros and the overpopulation on the range by using a variety of methods, including periodic gathers and removals, sex-ratio adjustments, and temporary fertility control vaccines like PZP Zonastat-H, PZP-22 vaccine pellets, and GonaCon. However, these methods have not proven effective at managing the population of wild horses and burros in the long-term or at all herd management areas and herd areas. For example, gathers and removals do not limit the ability of wild horses and burros to reproduce. And, for wild horses there is no currently available fertility control vaccine from which one dose reliably leads to substantial effects that last longer than two years (Rutberg et al. 2017, Baker et al. 2018, Carey et al. 2019). To cause long-lasting physiological effects, existing fertility control vaccines require repeated vaccine applications, which require sufficient budgetary and logistical resources (such as contractors qualified to conduct gathers) and can cause repeated stress to the animals as this generally involves capturing the animals. Capture and vaccination can be difficult for BLM to repeatedly perform at certain herd management areas and herd areas due to the areas' topography, size, skittishness of the horses, etc., on top of budgetary and logistical challenges.

In 2013, the National Research Council of the National Academies of Sciences (NAS) released a report titled "Using science to improve the BLM Wild Horse and Burro Program, a way forward." The NAS Report concluded that it could be useful to have a long-lasting fertility control method available for some situations for wild horse and burro management.

With regards to the duration of a fertility treatment's efficacy, the Report said:

> "Duration of fertility inhibition has major practical importance. Shorter-acting methods require substantially more effort and financial resources to implement even if the cost of the contraceptive itself is low. Longer-acting methods are preferable to minimize requirements for personnel and financial resources and to decrease the frequency of animal handling … In cases in which reversibility is important and repeated treatment is practical, one of the [existing] vaccines would be preferable, with the caution that treatment for more than a few years may prolong recovery of fertility. A single treatment that induces lifetime infertility could be preferable in other situations."

Since 2013, BLM has funded the development and testing of methods that could lead to long-lasting fertility control[1]. BLM's goal is to develop contraceptive treatments that achieve and maintain wild horse population sizes within the established AML, so as to reduce population growth rates in the short term, allow for increased time between gathers, and decrease the number of excess horses that must be removed from the range. The Proposed Action in this EA is designed to determine whether a one-dose oocyte growth factor (OGF) vaccine could be a reliable, long-lasting fertility control method. Oocyte growth factors are proteins that influence the development of oocytes (egg cells) in the ovary. If the one-dose OGF vaccine proves effective, it could be considered for use in future BLM wild horse and burro herd management actions, which management decisions would be subject to additional NEPA compliance.

Decreasing the number of excess wild horses on the range is consistent with findings and recommendations from the National Academy of Sciences (NAS), American Horse Protection Association (AHPA), The American Association of Equine Practitioners (AAEP), Humane Society of the United States (HSUS), Government Accountability Office (GAO), Office of Inspector General (OIG) and

[1] These include, but are not limited to, testing booster doses of GonaCon vaccine, intrauterine devices (IUDs), and new encapsulated formulations of PZP vaccine.

BLM policy; BLM notes that some of those non-governmental groups appear to advocate that removals should take place as part of a broader program that includes fertility control measures. The preface to the NAS report (2013) stated that "It is … evident that the consequences of simply letting horse populations, which increase at a mean annual rate approaching 20 percent, expand to the level of "self-limitation"—bringing suffering and death due to disease, dehydration, and starvation accompanied by degradation of the land—are … unacceptable." The GAO (2008) noted that "Populations that exceed AML can harm the health of the range….The overpopulation of wild horses and burros on the range may negatively impact herd health, rangeland health, and livestock and wildlife that depend on the range."

Contraception Vaccines in Wild Horse Management

As mentioned above, the WFRHBA specifically contemplates BLM using long-lasting fertility control, which could include sterilization, as a population control tool. 16 U.S.C. § 1333(b). No finding of excess animals is required for BLM to pursue contraception in wild horses or wild burros. *Id.*

In recent years, BLM has prioritized expanding the use of fertility control methods to slow population growth rates, reduce the overpopulation of wild horses on public lands, decrease the number of animals that BLM must gather and remove from the range, and protect rangeland ecosystem health. BLM has identified fertility control vaccines as a promising method of contraception. Contraception has been shown to be a cost-effective and humane treatment to slow increases in wild horse populations or, when used with other techniques, to reduce horse population size (Bartholow 2004, de Seve and Boyles-Griffin 2013, Fonner and Bohara 2017). A number of humane contraceptive methods exist, including but not limited to the use of fertility control vaccines (also called immunocontraception), intrauterine devices (IUDs), and humane sterilization techniques; each method has advantages and limitations. Contraception by itself does not remove excess horses from the range. Instead, successful contraception reduces future reproduction. So if a wild horse population is currently above AML, then further action may still be required to remove excess horses in order to achieve a thriving natural ecological balance.

Research to test the efficacy of contraceptive methods in wild horses is valuable to BLM because successful contraception that requires a minimum number of handling occasions would be expected to, among other things,: (1) slow the population growth rate; (2) reduce the frequency of horse gathers; (3) provide alternatives to the current fertility control vaccines which have limited duration of efficacy from one dose; and (4) lower wild horse management costs to taxpayers by reducing the frequency of gathers and lowering the number of horses that BLM must permanently remove and send to short- and long-term care facilities. Bartholow (2007) concluded that the application of 2 or 3-year contraceptives to wild mares could reduce operational costs in a project area by 12-20%, or up to 30% in carefully planned population management programs. Similarly, Hobbs et al. (2000) concluded that population suppression becomes more cost-effective if fertility control is long-lasting. Bartholow (2007) also concluded that contraceptive treatment would likely reduce the number of horses that must be removed in total, with associated reductions in the number of private placements and total holding costs.

Although fertility control treatments on individual wild horses may be associated with some potential physiological, behavioral, demographic, and genetic effects, those impacts are generally minor and transient (other than the temporary or long-lasting loss of reproductive potential for the treated individuals, which is the intended effect), do not prevent overall maintenance of a self-sustaining population, and do not generally outweigh the benefits of using contraceptive treatments in situations where it is a management goal to reduce population growth rates (Garrott and Oli 2013). The use of the oocyte growth factor vaccine for management of wild horses on the range, would be subject to a separate decision-making process and site-specific NEPA compliance, as informed by scientific information available at that time.

Development of a new fertility control vaccine is important as single doses of the existing vaccines are only reliably effective for up to two years. Rutberg et al. 2017, Baker et al. 2018, Carey et al. 2019. Two of the three fertility control treatments that the NAS identified in 2013 as being the "most promising" for immediate use were the porcine zona pellucida (PZP) and gonadotropin releasing hormone (GnRH) fertility control vaccines. Those vaccines were deemed promising partly because of the ease of their delivery method by injection, their availability, their relative efficacy, their lack of effects on scavengers that may eat carcasses of treated animals, and the fact that physiological side effects outside of the reproductive system are limited. Development of a new fertility control vaccine that confers long-lasting effects from a single injected dose would be another, potentially promising, tool for use in wild horse management. The OGF vaccine did not exist when the NAS reviewed fertility control methods available in 2013.

An additional reason that it is prudent to test new types of fertility control vaccines that can be used to manage wild horse populations is the small, but measurable, risk that PZP vaccine availability could be limited in the future, as a result of the growing global incidence of African swine fever. If that disease reaches the United States, then the supply of pig ovaries could be affected, and there may be restrictions on the movements of swine-derived tissues. African swine fever is not known to affect horses. An alternative to PZP would be recombinant zona pellucida (rZP) proteins, which are ZP molecules produced from genetically engineered microbes. Those could be used in vaccines but, as far as BLM is aware, the contraceptive effectiveness of any fertility control vaccines using rZP proteins has not yet been tested on mares in the United States.

Oocyte Growth Factor Vaccine

In 2019, BLM received a proposal from the USDA Animal and Plant Health Inspection Services National Wildlife Research Center (NWRC), for a study designed to test a one-injection formulation of a fertility control vaccine that had preliminary success when used in an earlier formulation that used four injections. If the one-dose formulation of the OGF vaccine is effective, then it could at least cause short-term infertility, and may be able to cause more long-term sterility in treated mares. If the effect lasts more than two or three years, then such a one-dose fertility control vaccine could be critically useful in reducing wild horse growth rates in BLM-administered herd management areas across the west. The research study proposed is responsive to the search for a long-lasting, "…single treatment that induces lifetime infertility…" as was alluded to by the 2013 NAS report.

The proposed study would assess the efficacy and contraceptive effectiveness of the one-dose OGF vaccine, but is not designed to assess behavioral effects of vaccination in free-roaming wild horses (since the study will be conducted on already gathered horses in a more confined environment). The previous four-injection version of the vaccine that would be used in this research has already been tested and appeared safe and successful (Appendix A). The one-treatment vaccine formulation in this research study would induce an immune response to the same oocyte growth factor proteins (called GDF9 and BMP15), but would use a different adjuvant (AdjuVac) and antigen packaging preparation (liposomes) to determine whether a single dose could have the same effect.

Fertility control vaccines meet BLM requirements for safety to mares and the environment (i.e., EPA 2009, 2012, 2013). The oocyte growth factor vaccine would constitute a new form of immunocontraceptive, but would have some of the same advantages that have been identified in other vaccines, including: because they work by causing an immune response in treated animals, there is no risk of hormones or toxins being taken into the food chain when a treated mare dies.

1.3 Purpose and Need for Action

The purpose of the Proposed Action is to test the efficacy of a vaccine against two oocyte growth factors, where the vaccine has been formulated to cause long-lasting contraception from a single dose, on

approximately 16 wild horse mares that have already been permanently removed from the range as excess animals. An equal number of untreated, control mares would live side by side with treated mares. A previously tested version of the vaccine caused contraception for at least 2 years, but it used a weak vaccine adjuvant that required four doses to be effective (results of that study are described in Appendix A).

This action is needed in order to determine whether the one-dose oocyte growth factor vaccine could be a reliable, longer- or long-lasting fertility control method for future BLM wild horse and burro herd management actions, that are subject to separate decisions by BLM and that are covered under separate NEPA documents. Conducting nondestructive research and seeking the recommendations of qualified scientists on matters related to wild horse and burro management is consistent with the provisions of the WFRHBA § 1333(b)(1) and 43 CFR § 46.210 (e).

1.4 Land Use Plan Conformance

The Proposed Action is in conformance with the Carson City Consolidated Resource Management Plan (2001) because it is consistent with national policy listed there to "…preserve and maintain a thriving natural ecological balance…" and with Standard Operating Procedure # 3, "*…contraceptive techniques may be used to slow the rate of an increase of wild horses within the HMAs."*

1.5 Relationship to Laws, Regulations, and Other Plans

Statutes and Regulations

The Proposed Action has been designed to conform with Federal regulations and other authorities that provide official and suggested guidance for management of wild horses by BLM.

1. ***Wild Free-Roaming Horses and Burros Act*** (WFRHBA) of 1971 (Pub. L. 92-195), as amended through the ***Public Rangelands Improvement Act*** of 1978 (Pub. L. 95-514). The Proposed Action is consistent with the WFRHBA specifically, but not limited to, the following:

"§ 1332. Definitions

(f) "excess animals" means wild free-roaming horses or burros (1) which have been removed from an area by the Secretary pursuant to application law…

§ 1333. Powers and duties of the Secretary.

(b) Inventory and determinations; consultation; overpopulations; research study; submittal to Congress.

(1) The Secretary shall … determine whether appropriate management levels should be achieved by the removal or destruction of excess animals, or other options (such as sterilization, or natural controls on population levels). In making such determinations the Secretary shall consult with the United States Fish and Wildlife Service, wildlife agencies of the State or States wherein wild free-roaming horses and burros are located, such individuals independent of Federal and State government as have been recommended by the National Academy of Sciences, and such other individuals whom he determines have scientific expertise and special knowledge of wild horse and burro protection, wildlife management and animal husbandry as related to rangeland management.

(3) For the purpose of furthering knowledge of wild horse and burro population dynamics and their interrelationship with wildlife, forage and water resources, and assisting him in making his determination as to what constitutes excess animals, the Secretary shall contract for a research study of such animals with such individuals independent of Federal and State government as may be recommended by the National Academy of Sciences for having scientific expertise and special knowledge of wild horse and burro protection, wildlife management and animal husbandry as related to rangeland management."

The Proposed Action includes the use of a fertility control vaccine that may cause short-term contraception, long-term-contraception, or sterilization. The wild horses that will take part in the study have been previously determined to be excess animals and were already removed from the wild, as a

result of previous BLM NEPA determinations. The proposed action makes use of USDA APHIS NWRC expertise in animal fertility control methods.

2. ***Federal Land Policy and Management Act*** (Pub. L. 94-579), as amended
The Proposed Action studies a fertility control method that should slow wild horse population growth rates and, therefore, aid BLM in management on the basis of multiple use and sustained yield as described in the FLPMA.

3. ***Wild Free-Roaming Horse and Burro Management*** (43 C.F.R. § 4700)
The Proposed Action is consistent with 43 CFR 4700 specifically, but not limited to, the following:
"4710.4. Constraints on management: Management shall be at the minimum level necessary to attain the objectives identified in approved land use plans and herd management area plans."

The Proposed Action would determine whether a one-dose vaccine could lead to long-term fertility control in wild horses. Currently available fertility control vaccines require more than one dose to have long-lasting effects. Therefore, if the one-dose OGF vaccine is effective in causing long-term infertility, its use could reduce the amount of animal handling that would be required, compared to available vaccines.

4. ***BLM Wild Horses and Burros Management Handbook*** (BLM H-4700-1)
Guidelines in the BLM management Considerations handbook are not legally binding policy, but they do provide suggestions for BLM management. The Proposed Action is consistent with handbook H-4700-1 specifically, but not limited to, the following:
"4.5.3. Reduce Population Growth Rates: "Additional management alternatives (tools) may be considered in the future, pending further research."
"8.1 Other research projects may be initiated as needed to support the management of WH&B."
"8.2 A National Research Advisory Team exists to review research proposals, monitor research project progress, update the Strategy as necessary, and provide recommendations to the WH&B Division Chief…All requests for research and/or research proposals pertaining to the Wild Horse and Burro program, whether generated from the field or through field-related contacts, are to be directed to the Research Advisory Team for review."

The Proposed Action includes the testing of a new fertility control method (one-dose OGF vaccine), which would be responsive to current wild horse management needs, which still include long-lasting fertility control methods that require only one handling occasion. Since the time that handbook H-4700-1 was written, a study at the Northern Nevada Correctional Center (NNCC) revealed that pelleted PZP did not provide adequate long-lasting contraceptive effect. The research proposal from NWRC was reviewed by the BLM WHB Research Advisory Team, which provided a recommendation to the WHB Division Chief.

5. ***BLM Management Considerations*** (BLM H-4710-1)
Guidelines in the BLM management Considerations handbook are not legally binding policy, but they do provide suggestions for BLM management. The Proposed Action is consistent with handbook H-4710-1 specifically, but not limited to, the following:
".5 Research.
.51 Strategic Research Plan. The BLM shall conduct wild horse and burro research in accordance with the priorities identified in the Strategic Research Plan for Wild Horse and Burro Management."

Handbook H-4710-1 refers to the BLM Wild Horse and Burro Strategic Research Plan (BLM 2005), which includes the following guidance: "…the BLM seeks a contraceptive agent that lasts three to five

years following a single injection….Reproduction in wild horses may differ in a number of subtle ways from domestic horses, for example, in the season of estrus cycles. The explanation for these observed differences may be merely environmental, or there may be some minor physiological differences that are inherited. Until the differences can be defined, the BLM has determined that non-invasive research into fertility control could be conducted on captured wild horses held in BLM facilities…" If it is successful, the one-dose OGF vaccine may deliver a form of fertility control that may last three to five years, or longer. The Proposed Action would test the one-dose OGF vaccine in wild horses, in a BLM-contracted facility (the NNCC).

6. ***Comprehensive Animal Welfare Program*** (BLM IM 2015-151)
The Proposed Action is consistent with this policy. Animals in the study will be maintained and cared for in keeping with BLM Comprehensive Animal Welfare Program (Appendix C).

7. ***Animal Health, Maintenance, Evaluation, and Response*** (BLM IM 2015-070)
The Proposed Action is consistent with this policy. Any decision to humanely euthanize animals would be made in conformance with this policy. Euthanasia of otherwise-healthy animals is not a planned part of the Proposed Action.

In addition to the above, the Proposed Action is also consistent with 43 C.F.R. § 46.210, and does not meet any extraordinary circumstance that would require further NEPA review. Despite BLM's conclusion that a Categorical Exclusion could have been an appropriate vehicle for NEPA compliance, BLM Nevada chose to analyze the Action Alternative in an EA to allow for additional public input after publication of a preliminary EA.

1.6 Decision to be Made

The authorized officer would determine whether or not to approve the Proposed Action. The authorized officer's decision is limited to whether to conduct the study. The decision would not set any precedent for use of the vaccine in any future BLM wild horse and burro herd management actions, though preliminary or final results of the proposed study could be taken into consideration in future BLM NEPA determinations.

1.7 Scoping and Identification of Issues

The following issues were identified as a result of internal scoping relative to the BLM's management of wild horses in the planning area:

Impacts to individual wild horses included in the Proposed Action. Measurement indicators for this issue include:

- Expected impacts of handling stress to individual wild horses
- Expected effects of proposed fertility control vaccination
- Potential impacts to animal health and condition
- Potential impacts to pregnant mares and foals
- Potential impacts of vaccination on adoptability

2.0 Description of the Alternatives

2.1 Introduction

This section of the EA describes the Proposed Action and alternatives, including any that were considered but eliminated from detailed analysis. Two alternatives are considered:

- Alternative 1: Proposed Action – Treat approximately 16 mares with oocyte growth factor vaccine and determine efficacy during a three-year study.
- Alternative 2: No Action — Do not conduct the proposed study.

The Proposed Action Alternative was developed to respond to the Purpose and Need. The No Action Alternative would not achieve the identified Purpose and Need. However, it is analyzed in this EA to provide a basis for comparison with the Action Alternative, and to assess the effects of not conducting the proposed study at this time.

2.2 Description of Alternatives Considered in Detail

2.2.1 Management Actions Common to Alternatives 1-2

Whether or not the Proposed Action is taken, the wild horses in the study will be housed and maintained at the Northern Nevada Correctional Center (NNCC) until they are adopted or sold according to existing BLM policy, or are moved to a different off-range facility. BLM contracts with NNCC for the maintenance and care of excess wild horses removed from the range.

2.2.2 Proposed Action

The Proposed Action would include a study designed to test the efficacy of a modified fertility control vaccine in excess wild mares, over a three-year period. This study research is needed to improve the understanding of the effects of a new vaccine that is specific to two ovarian proteins, and which has been designed to be effective after just one dose. The vaccine would be administered as a single injection to the mares in the treatment group.

The one-dose formulation of ovarian growth factor vaccine would include two antigens, BMP15 and GDF9, that have been identified as having a role in oocyte development in the ovary (Galloway et al. 2000, Eckery et al. 2002, Appendix A). These protein antigens would be conjugated to a carrier protein, keyhole limpet hemocyanin (KLH; Curtis et al. 2008), to increase the presentation and longevity of antigen epitopes to the vaccinated mares' immune system. To prolong the immune response further, some or all of the antigen and carrier molecules will be enclosed in spherical, phospholipid bilayer molecules known as liposomes; liposome molecules are a feature of the SpayVac vaccine (Bechert et al. 2013). The adjuvant used to enhance immune response would be one that has been tested and used as a component in other NWRC vaccines, AdjuVac, which contains a small amount of *Mycobacterium avium* as an immunostimulant (Miller et al. 2004). Vaccine success would be measured in terms of the response including at least short-term infertility, with longer-term sterility in treated mares also being a desirable outcome.

Notwithstanding the stated start dates in Appendix A, the timing of the start of the study may depend on administrative factors. The NNCC was selected as a suitable site for the study because it houses and works with excess wild horses removed from the range and has pen designs that are ideal for fertility control studies. The pens are constructed with sturdy materials and high walls, appropriate for housing stallions. These pens have been successfully used in a BLM-funded 2011-2013 pen trial of pelleted versions of a PZP vaccine that also included wild horse mares and stallions in breeding groups that would be similar to the proposed OGF vaccine study design. The same pens at NNCC used for the previous study would be used for the proposed OGF vaccine study.

Research done in coordination with US Department of Agriculture (USDA) Animal Plant Health Inspection Services (APHIS) National Wildlife Research Center (NWRC) would include:

- Treatment of approximately 16 mares with the fertility control vaccine;
- Non-treatment of approximately 16 mares to serve as untreated, 'control' animals;
- Maintenance of mares, in stable groups of 4 treated mares and 4 control mares, with one fertile stallion at a time;

- Periodic blood sampling for hormone and antibody characterization;
- Periodic pregnancy checking via transrectal palpation or ultrasound examination, conducted by a qualified reproductive professional.

Animal care would meet BLM standards identified in the Comprehensive Animal Welfare Program (Appendix C). Holding pens would be approximately 200 feet by 100 feet, with 8 foot tall solid panel fencing. Fertile stallions would be rotated in with mare groups approximately every 3-4 months. To increase the probability that any potentially fertile mares (whether vaccinated or untreated) become pregnant, fertile stallions will be periodically rotated in and out of the bands of stable mares. It is expected that this would happen approximately every 3-4 months. In cases where a mare becomes pregnant, the BLM will take appropriate measures for the safety, welfare, care and handling of pregnant mares and their foals. Approximately 16 mares will receive the one-dose OGF vaccine, and will be monitored throughout the three-year study. The same number of non-pregnant control animals (approximately 16) will be present at the start of each year of the study; to accommodate this need, additional 'control' animals could be added to the study each year as necessary to maintain the sample size of 'control' mares at the start of each year.

The following animal selection stipulations would apply:

- The starting target score for Henneke body condition will be at least 4 for both mares and stallions;
- Mare and stallion ages at the start of the study will be between 3-10 years old;
- Random selection will be used to place mares in either the vaccine-treated group or the untreated control group.

Other Stipulations:

- Guidelines as set forth in the Comprehensive Animal Welfare Program (Welfare Assessment Standards for Gathers) will be followed.
- Individuals handling the vaccine will take standard precautionary steps used when handling any vaccine, to minimize the risk of needle sticks. Out of an abundance of caution, for this study no female humans of childbearing age or younger will be involved with the handling or injection of vaccine.
- During operations, the Lead Contracting Officers Representative (COR) for the BLM contract with the NNCC would be present, or would delegate supervision duties to another BLM employee.
- The BLM contract Veterinarian associated with the NNCC facility, Animal and Plant Health Inspection Service (APHIS) Veterinarian or other licensed Veterinarian would be on call or on site.
- Decisions to humanely euthanize animals would be made in conformance with BLM policy (BLM Washington Office Instruction Memorandum 2015-070).

2.2.3 Alternative 2: No Action

Alternative 2 would be to not test the efficacy of the oocyte growth factor vaccine. This Alternative would not meet the Purpose and Need identified in section 1.3. BLM would not be able to gather information about the long-term efficacy of the oocyte growth factor vaccine that has been formulated for a single injection. Available information about effects of oocyte growth factor vaccines would remain limited to the previous studies that demonstrated the effectiveness of a vaccine administered over four injections, rather than for the single injection formulation.

2.3 Alternatives Considered but Dismissed from Detailed Analysis

2.3.1 PZP Vaccine Study

An alternative in which a PZP vaccine would be tested in a pen trial at NNCC was not considered for detailed analysis. This alternative was not analyzed because BLM has already supported pen trials for two types of PZP vaccine formulations that were intended to cause long-lasting effects from a single dose of vaccine. BLM supported pen trials testing fertility rates of wild mares inoculated with SpayVac vaccine; the mares and fertile stallions were housed at the Pauls Valley, Oklahoma, BLM corral (Roelle et al. 2017). Similarly, nominally long-lasting formulations of PZP vaccine pellets were tested in pen trials at the NNCC from 2011 to 2014, in the same pens that would be used in the Proposed Action, and using similar methods for rotation of fertile stallions with bands of treated and non-treated mares. Results of the most recent trials for both SpayVac (in Oklahoma) and the nominally long-lasting PZP vaccine pellet formulations (at NNCC) did not cause an extended period of infertility, and were discontinued after higher than expected pregnancy rates were observed in treated mares after a short time period (Roelle unpublished results, Turner unpublished results). An additional PZP vaccine trial would not be responsive to the purpose and need identified in this EA, and would not provide BLM with information about a new type of fertility control vaccine that would be free of risk from possible disruptions that could be caused by any future outbreak of African swine fever.

2.3.2 GonaCon Vaccine Study

An alternative in which the GonaCon vaccine would be tested in a pen trial at NNCC was not considered for detailed analysis. An additional GonaCon vaccine trial would not be responsive to the purpose and need identified in this EA. GonaCon is approved for use as a fertility control vaccine in wild horses and burros (EPA 2013). However, this alternative was not analyzed because field trials have already demonstrated that GonaCon is an effective vaccine, with potential for long-lasting efficacy after a second hand-injected dose is administered (Baker et al. 2018). BLM has been supporting an ongoing field trial in Theodore Roosevelt National Park, North Dakota, that aims to determine optimal dose timing and long-term efficacy of GonaCon booster doses. The physiological and contraceptive effects of GonaCon are fairly well understood, and another pen trial with wild horses is not needed for BLM to use this vaccine in wild horse management.

2.3.3 Oocyte Growth Factor Vaccine Study in Domestic Mares

An alternative where the proposed study would take place with domestic horses outside of BLM custody was dismissed from detailed study for several reasons. Most importantly, wild horses are the intended population of use for the vaccine. The vaccine should work in wild horses; it is possible that some phenotypic or physiological traits that are idiosyncratic to wild horses may influence vaccine effectiveness, as noted in the WHB Strategic Research Plan (BLM 2005). Unlike domestic horses, most wild horses have not typically been exposed to numerous vaccines over the course of their lives. There is some possibility that the oocyte growth factor vaccine could interact with the immune system of wild horses in a way that is different from how it interacts with the immune system of domestic horses.

3.0 Affected Environment

This section of the EA briefly discusses the relevant components of the human environment which would be either affected or potentially affected by the Proposed Action or No Action Alternative (refer to Table 2). Direct impacts are those that result from the management actions while indirect impacts are those that exist once the management action has occurred.

3.1 General Description of the Affected Environment

The NNCC is a Nevada state prison facility located on non-federal lands, within Carson City County, Nevada. The topography at NNCC is flat, at an elevation of approximately 4,680 feet. Precipitation in the region of Carson City municipality averages 9.6 inches. Temperatures also vary, from average high

temperatures around 90 degrees Fahrenheit in July to average low temperatures around 22 degrees Fahrenheit in December.

The NNCC grounds include equine facilities suitable for wild horse care, maintenance, and handling by inmates. The facilities include a number of large pens, including eight 100 foot by 200 foot pens that have 8 foot high, smooth steel walls made of highway-grade collision railing. There are runways between all pens that lead to sorting pens. Animals can be humanely moved into runways leading to a padded hydraulic squeeze chute that is suitable for inspections and veterinary care. The nearest public lands are approximately a half mile east of the animal maintenance and handling areas on the NNCC.

There is no public access to the areas of the NNCC where the study would take place, as this area is accessible to inmates and with limited visibility from the security watchtower. Because these are areas with inmate presence, there is no photography, recording or videography allowed in the wild horse maintenance and handling areas of the NNCC. When BLM staff periodically visit the animal maintenance and handling areas of the NNCC, the NNCC requires that any cameras and/or cell phones be left behind and that they be accompanied by a special security escort. Although there are scheduled wild horse and burro adoption events held on NNCC grounds that are open to the public, those events are held in an area where public safety can be ensured. The adoption area has additional security staff are present and are either in uniform or plain clothing, visitors pass through a security check point, the area is apart from where the inmates work, and is separate and distinct from the area where the horses in the study would be housed, cared for by the inmates, vaccinated, and checked for pregnancy.

3.2 Description of Affected Resources/Issues

Table 2 lists the elements of the human environment subject to requirements in statute, regulation, or executive order which must be considered.

Table 2: Supplemental Authorities (Critical Elements of the Human Environment)

Supplemental Authorities	Present	Affected	Rationale
ACECs	**NO**	**NO**	Not present.
Air Quality	**NO**	**NO**	The planning area is within an established prison facility where horses are already housed. The Proposed Action would have no measurable influence on air quality.
Cultural Resources	**NO**	**NO**	Not present.
Environmental Justice	**NO**	**NO**	Not present.
Fish Habitat	**NO**	**NO**	Not present.
Floodplains	**NO**	**NO**	Not present.
Forest and Rangelands	**NO**	**NO**	Not present.
Migratory Birds	**YES**	**NO**	The planning area is within an established prison facility where horses are already housed. Although some migratory birds may occasionally be present on the grounds, the Proposed Action would have no measurable influence on migratory birds.
Native American Religious Concerns	**NO**	**NO**	None known.
Noxious Weeds	**YES**	**NO**	The planning area is within an established prison facility where horses are already housed. The proposed action would have no measurable influence on noxious weeds.
Prime or Unique Farmlands	**NO**	**NO**	Not present.

Riparian-Wetland Zones	**NO**	**NO**	Not present.
T&E Species	**NO**	**NO**	Not present.
Water Quality	**YES**	**NO**	The planning area is within an established prison facility where horses are already housed. The Proposed Action would have no measurable influence on water quality.
Waste (Hazardous or Solid)	**NO**	**NO**	Not present.
Wild and Scenic Rivers	**NO**	**NO**	Not present.
Wilderness and Wilderness Study Area	**NO**	**NO**	Not present.

There are no critical elements of the human environment identified as present and potentially affected by the Proposed Action or by the No Action Alternative. The Proposed Action would take place on the grounds of the Northern Nevada Correctional Center, in an area that does not include any federal lands. In addition to the critical elements listed in Table 2, the only resources that may be affected by the Proposed Action are wild horses that would be included in the proposed action. The affected environment, relative to wild horse resources, is described below.

3.2.1 Wild Horses

Any wild horses included in the Proposed Action would have been previously gathered and removed from the public range as excess animals. They would have arrived at the NNCC as a part of their off-range care. The length of time since the horses were removed from the range may vary by individual animal. Their ages would be between 3-10 years old at the time of the start of the Proposed Action, and their Henneke body condition scores would be at least 4. Any stallion that would be included in the study would still be fertile. To the extent possible, potentially fertile mares would be identified as candidates to be included in the study; this determination could be from BLM records about whether the mare had a foal at her side when she was initially gathered, or if information is available about the mare's current pregnancy status. All animals at the NNCC, whether included in the proposed study or not, are properly fed and watered, consistent with the standards for their maintenance and care.

4.0 Environmental Consequences

4.1 Introduction

This section of the EA documents the potential environmental impacts which would be expected with implementation of the Proposed Action and/or the No Action Alternative. These include the direct impacts (those that result from the management actions) and indirect impacts (those that exist once the management action has occurred).

4.2 Predicted Effects of Alternatives

The direct and indirect impacts to these resources which would be expected to result with implementation of the Proposed Action or No Action Alternative are discussed in detail below.

4.2.1 Wild Horses

Impacts of Proposed Action Alternative

Under the Proposed Action Alternative, impacts to wild horses could be both direct and indirect, occurring to individual horses included in the study. All the wild horses that would be included in the study would have been previously gathered and removed from the public range as excess, and the impacts of gathering, transporting, holding, and adopting horses would have been considered in the NEPA analyses supporting the BLM decisions that led to their gather. The impacts analysis that follows is limited to potential impacts that could result from the Proposed Action; it does not include the impacts of

already-analyzed BLM actions that led the horses being housed at the NNCC, or actions that resulted directly from their prior gathering.

Animal Handling

There is the potential for direct impacts to occur, associated with having wild horses living in a corral setting. Under past management practices, captured mares experienced elevated stress from handling (Ashley and Holcombe 2001), but BLM has instituted guidelines to reduce the sources of handling stress (BLM 2015). The CAWP (Appendix C) would be implemented to ensure that conditions for animal care and welfare are safe and humane, and to minimize potential stress and injury to wild horses. Handling may include freeze-marking, for the purpose of easily identifying individual animals.

It is possible that there could be conflict between individual animals that live together in pens. Such impacts are known to occur intermittently in holding facilities. An example of an indirect individual impact could be a brief 1-2 minute skirmish between animals; usually such conflicts are between studs, and would not be expected in bands with only one stud and eight mares. Injuries typically involve a bite or a kick that bruises, but does not break, the skin. The frequency of this type of minor impact would vary across individual animals. There is the potential for conflict after introduction of new stallions to a group of mares, but the expectation is that the level of that conflict will be low, based on previous experience at the NNCC. The same pens at NNCC that would be used for the proposed study were previously used in a 2011-2013 pen trial of pelleted versions of a PZP vaccine. In that trial, up to 18 mares and one stallion at a time were held per pen, and with stallions rotated to ensure that mares were exposed to fertile stallions. Despite the density of animals in that study being about twice as high as proposed for the OGF vaccine study, no injuries to mares, foals, or stallions were mentioned in progress reports or the final report from that work (Turner, unpublished reports to BLM).

Mares in the Proposed Action that are not treated with the oocyte growth factor vaccine would remain fertile, and would likely become pregnant and produce foals. With 16 untreated mares in the Proposed Action, it is possible that as many as 16 foals could be born per year to these mares, over the course of the 3-year study. Some number of foals may also be born to mares treated with the vaccine.

Foals born to wild mares in the NNCC would have wild horse legal status, and would stay with their mother through the age of weaning (typically 6 months or older). BLM would seek to place these foals into private care through adoption. Researchers may examine or draw blood from foals to determine their reproductive development. It is not expected that either a vaccine-treated or an untreated mare would reject a foal; mares would be living in bands with the same set of other females throughout the study. If a mare dies or must be humanely euthanized during the study, every effort would be made to provide appropriate care to orphaned foals. Veterinarians may administer electrolyte solutions or orphan foals may be fed milk replacer as needed to support their nutritional needs. Orphan foals may be placed in a foster home in order to receive additional care.

In the event of injury or health concerns, any decisions to humanely euthanize animals would be made in conformance with BLM policy. BLM Euthanasia Policy IM-2015-070 is used as a guide to determine if animals meet the criteria and should be euthanized.

Fertility Control Vaccine Direct Effects

All fertility control methods in wild animals are associated with potential risks and benefits, including effects of handling, frequency of handling, physiological effects, behavioral effects, and reduced population growth rates (Hampton et al. 2015). In any vaccine, the antigen molecules are a stimulant to which the body responds with a primary immune response, including the generation of antigen-specific antibodies. Those antibodies can later lead to an immune response that reduces the relative bioavailability of the antigen molecules in the body. Adjuvants are additional substances that are included in vaccines to

elevate the level of immune response. Adjuvants help to strengthen immune responses, and can foster a long-lasting immune response that is specific to the antigen.

Each treated mare would receive a single dose of the oocyte growth factor vaccine. The intended purpose of this vaccine is to cause long-term infertility. Vaccination in this study would be given as a one-time intramuscular injection, by hand. Because the vaccine is designed to impair female fertility, the oocyte growth factor vaccine will not be handled by human females during this study. The vaccine formulation would include GDF9 and BMP 15 proteins conjugated to KLH molecules, encapsulated within liposomes. The vaccine also would include the Adjuvac adjuvant (Miller et al. 2004). Treated mares could experience immune responses to any of those vaccine components. There may be transiently elevated body temperature and injection site soreness.

Most mares recover quickly from the stress of handling, and none is expected to suffer serious long term effects from the injections, other than the direct consequence of temporary or permanent infertility, which is the desired outcome of the vaccination. The oocyte growth factor vaccine should stimulate a persistent immune response resulting in prolonged antibody production against the oocyte growth factors BMP15 and GDF9, the KLH carrier protein, and the adjuvant (Appendix A). Elevated levels of antibodies that are specific against BMP15 and GDF9 should follow vaccination with oocyte growth factor vaccine, which in turn attenuates and disrupts oocyte and / or follicular development (Appendix A). Changes associated with ovarian growth factor vaccination should lead to measurable changes in ovarian structure and function, with the result that ovulation ceases. Specifically, a combined vaccination against both GDF9 and BMP15 appears to cause premature, but incomplete development of follicles in such a way that they do not develop into fully competent ovulatory follicles (Appendix A). Another specific result of vaccination is a lack of observed estrous cycling (Appendix A). There may also be associated changes in hormone concentrations and related physiological effects, consistent with a lack of ovulation and estrus. Preliminary data from a combined oocyte growth factor vaccine against BLM15 and GDF9 indicated that there was a prolonged lack of estrus in mares, even after the level of these antibodies decreased (Appendix A). The effects of the one-dose OGF vaccine, whether temporary or long-lasting, are expected to be comparable to what is observable in mares' seasonal anestrous period, in that during shorter days of fall, winter and early spring, the ovaries are minimally active. Often during that time period small follicles develop but none ovulate. Hormonal changes (gonadal estrogen and progesterone) resulting from OGF vaccination are expected to be consistent with changes that occur naturally both annually, during the shorter days of the non-breeding season, and those that take place in older mares that have reached reproductive senescence (and which, therefore, are no longer cycling). In principle, it is possible that the effects of vaccination may lead to a lifelong dysregulation of oocytes or their growth factors from the ovaries; this would be a form of vaccine-induced sterility.

Treated mares may become only temporarily infertile, or may remain infertile for many years. Of the 10 mares treated with the multi-injection oocyte growth factor vaccine against GDF9 and BMP15 (Appendix A), all 10 were infertile in the first year after vaccination, and 9 of 10 were infertile in the second year (NWRC, unpublished data). Over the course of the proposed 3-year study, it may not be possible to determine whether the one-dose version of the oocyte growth factor vaccine would cause permanent sterility, because mares can live well over 20 years.

If the oocyte growth factor vaccine causes permanent infertility in some or all of treated mares, then that would be consistent with the desired contraceptive effect, and would be similar in outcome to mares treated multiple times with existing PZP vaccines to suppress reproduction, where some horses can become sterile from repeated multiple PZP doses.

Injection site reactions associated with immunocontraceptive treatments are possible in treated mares, as has been seen in mares treated with PZP vaccines (Roelle and Ransom 2009, Joonè et al. 2017) or with

GnRH vaccines (Goodloe 1991, Miller et al. 2008. Roelle and Ransom 2009). The one-dose oocyte growth factor vaccine that would be used in the Proposed Action would include the Adjuvac adjuvant, which is also a component of GonaCon vaccine. As associated with its use in GonaCon, the Adjuvac adjuvant is known to have the potential to cause injection site reactions whether injection is by hand or via darting. Reactions may include some minor degree of inflammation, swelling, and the potential for subcutaneous sterile abscesses, or purulent abscesses, at the injection site (Powers et al. 2011, Baker et al. 2018). Miller et al. (2008) noted that the water and oil emulsion in GonaCon will often cause cysts, granulomas, or sterile subcutaneous abscesses at injection sites; in some cases, a sterile abscess may develop into a draining abscess. In elk treated with GonaCon, Powers et al. (2011) noted up to 35% of treated elk had an abscess, despite the injection sites first being clipped and swabbed with alcohol. Even in studies where swelling and visible abscesses followed GonaCon immunization, the longer term nodules observed did not appear to change any animal's range of movement or locomotor patterns (Powers et al. 2013, Baker et al. 2017, Baker et al. 2018).

It is not expected that the oocyte growth factor vaccine would cause miscarriage in pregnant mares, because the oocyte growth factors that are included in the vaccine are not thought to play a role in fetal development, other than perhaps in ovarian development. A comparison of any observed miscarriage rates in treated and untreated mares could be used to quantify such an effect, if it occurs. Observations following gather operations indicate that the rate of miscarriage varies, but can occur in about 1 to 5% of the captured mares, particularly if the mares are in very thin body condition or in poor health. However, as any mares included in this study would not have been immediately gathered, and their body condition would be at least 4, any miscarriage rate would be expected to be lower. There is some possibility that the fetuses of treated mares would have compromised ovarian function, but this is unlikely because maternal antibodies do not typically cross the placental barrier. Nursing foals may be exposed to oocyte growth factor antibodies in colostrum but antibodies in colostrum do not typically lead to lifelong innate immune responses in nursing offspring.

Infanticide is a rare but natural behavior that has been observed in wild equids (Feh and Munktuya 2008, Gray 2009), but there are no published accounts of infanticide rates increasing as a direct result of fertility control vaccine application in wild horse or burro herds. "Foal stealing," where a near-term pregnant mare steals a neonate foal from a weaker mare, is unlikely to be a common behavioral result of including fertility control vaccine treated mares in a wild horse herd. Any suggestion that there would be a connection between fertility control treatment and "foal stealing" would be speculative, as there has not been any published record of that in a peer-reviewed study. McDonnell (2012) noted that "foal stealing is rarely observed in horses, except under crowded conditions and synchronization of foaling," such as in horse feed lots with extremely high density. Those conditions are not present at NNCC, where pregnant mares will be in large pens with a small number of other animals present, and where the expectation is that any parturition dates would be distributed across the normal foaling season. Killian et al. (2008) conducted a pen trial of several fertility control methods at the NNCC and did not report any signs of infanticide or "foal stealing."

Fertility Control Vaccine Indirect Effects

One expected long-term, indirect effect on wild horses treated with a successful fertility control vaccine would be an improvement in the mares' overall health. This result has been observed in mares treated with PZP vaccine (Turner and Kirkpatrick 2002). Many treated mares would not experience the biological stress of pregnancy, foaling and lactation. An observable measure of improved health is high body condition scores (i.e., Nuñez et al. 2010). If a treated mare returns to fertility, her future foals would be expected to be healthier overall, and would be expected to benefit from improved nutritional quality in the mare's milk. Past application of fertility control vaccines has shown that mares' overall health and body condition remains improved even after fertility resumes. Other types of fertility control vaccine treatment may increase mare survival rates, leading to longer potential lifespan (Turner and Kirkpatrick 2002,

Ransom et al. 2014a). Anecdotal BLM observations of mares treated in past gathers showed that many of the treated mares were larger than, maintained higher body condition than, and had larger healthy foals than untreated mares.

Vaccination with ovarian growth factor vaccine may lead to behavioral effects that are consistent with a lack of estrus. Davis et al. (2018) observed reduced estrus behavior in mares vaccinated with either a GDF9 vaccine or a BMP15 vaccine. However, lack of estrus behaviors does not imply that treated mares will not maintain social relations with other horses. A near lack of estrus behaviors has also been observed in mares vaccinated with a different fertility control vaccine, GonaCon; such a lack of estrus behaviors is very similar to what can be observed in pregnant mares (Ransom et al. 2014b, Baker et al. 2018). In those studies, treated free-roaming mares continued to maintain social relationships with other horses in established social bands. Similarly, free-roaming mares that lacked ovaries appeared to maintain social activity insofar as those mares were always observed with bands of other horses (Collins and Kasbohm 2017).

Mares treated with the oocyte growth factor vaccine may have long-lasting granulomas at the vaccine injection site. This outcome has been observed in mares treated with GonaCon, which is another vaccine with the Adjuvac adjuvant. It is conceivable that mares with granulomas or small visible scars may be more difficult to place into private care in the future. However, the magnitude of any such effect would likely be small, considering that wild horses often have a number of other scars and marks resulting from earlier life events.

The proposed study would not lead to the loss of ovaries in any treated animals. Nonetheless, based on the analogy that removal of ovaries would lead to complete loss of ovarian function, it is possible to make some inferences from literature related to ovariectomy. However, considering that the ovaries would remain in OGF vaccine treated horses, the analogous physiological effects in OGF treated mares would likely be less pronounced than in ovariectomized mares. Even under removal of ovaries – which would not happen in the proposed study – substantial bone density loss would not be expected in wild horses living in conditions such as in the proposed study, or in off-range pastures. The BLM knows of no scientific, peer-reviewed literature that documents bone density loss in mares following ovary loss. A concern has been raised in an opinion article (Nock 2013) that ovary removal in mares could lead to bone density loss. That paper was not peer reviewed nor was it based on research in wild or domestic horses, so it does not meet the BLM's standard for "best available science" on which to base decisions (Kitchell et al. 2015). Hypotheses that are forwarded in Nock (2013) appear to be based on inferences from modern humans leading sedentary lives. Post-menopausal women have a greater chance of osteoporosis (Scholz-Ahrens et al. 1996), though some estrogen is also produced in tissues outside the ovaries. Bone loss in humans has been linked to reduced circulating estrogen. There have been conflicting results when researchers have attempted to test for an effect of reduced estrogen on animal bone loss rates in animal models; all experiments have been on laboratory animals rather than free-ranging wild animals. While some studies found changes in bone cell activity after ovariectomy leading to decreased bone strength (Jerome et al. 1997, Baldock et al. 1998, Huang et al. 2002, Sigrist et al. 2007), others found that changes were moderate and transient or minimal (Scholz-Ahrens et al. 1996, Lundon et al. 1994, Zhang et al. 2007) and even returned to normal after 4 months (Sigrist et al. 2007). Consistent and strenuous use of bones, for instance using jaw bones by eating hard feed, or using leg bones by travelling large distances, appears to limit the negative effects of estrogen deficiency on micro-architecture (Mavropoulos et al. 2014). The effect of exercise on bone strength in animals has been known for many years and has been shown experimentally (Rubin et al. 2001). Dr. Simon Turner, Professor Emeritus of the Small Ruminant Comparative Orthopaedic Laboratory at CSU, conducted extensive bone density studies on ovariectomized sheep, as a model for human osteoporosis. During these studies, he did observe bone density loss on ovariectomized sheep, but those sheep were confined in captive conditions, fed twice a day, had shelter from inclement weather, and had very little distance to travel to get food and water

(Simon Turner, CSU Emeritus, written comm., 2015). Dr. Turner indicated that an estrogen deficiency (i.e., such as might happen if a mare had no ovaries) could potentially affect a horse's bone metabolism, just as it does in sheep and human females when they lead a sedentary lifestyle, but indicated that the constant weight bearing exercise, coupled with high exposure to sunlight ensuring high vitamin D levels, are expected to prevent bone density loss (Simon Turner, CSU Emeritus, written comm., 2015). A horse would have to stay on stall rest for years after removal of the ovaries in order to develop osteoporosis (Simon Turner, CSU Emeritus, written comm. 2015; a stall is a small enclosed space in which an animal cannot move more than a few feet in any given direction). Wild horses that would be involved with the proposed study would neither lose their ovaries, nor be on stall rest.

Two studies raise the concern that treatment with immunocontraceptives could possibly lead to an evolutionary increase in the frequency of individuals whose genetic composition fosters weak immune responses (Cooper and Larson 2006, Ransom et al. 2014a). Many factors influence the strength of a vaccinated individual's immune response, potentially including genetics, but also nutrition, body condition, and prior immune responses to pathogens or other antigens (Powers et al. 2013). The concern is based on an assumption that lack of response to any given fertility control vaccine is a highly heritable trait, and that the frequency of that trait will increase over time in a population with a high fraction of vaccine-treated animals. Cooper and Herbert (2001) reviewed the topic, in the context of concerns about the long-term effectiveness of immunocontraceptives as a control agent for exotic species in Australia. They posit that imunocontraception could be a strong selective pressure, and that selecting for reproduction in individuals with poor immune response could lead to a general decline in immune function in populations where such evolution takes place. Other authors have also speculated that differences in antibody titer responses could be partially due to genetic differences between animals (Curtis et al. 2001, Herbert and Trigg 2005). However, Magiafolou et al. (2013) clarify that if the variation in immune response is due to environmental factors (i.e., body condition, social rank) and not due to genetic factors, then there will be no expected effect of the immune phenotype on future generations. It is possible that general health, as measured by body condition, can have a causal role in determining immune response, with animals in poor condition demonstrating poor immune reactions (NAS 2013). Correlations between physical factors and immune response would not preclude, though, that there could also be some degree of a heritable response to immunocontraception. In studies not directly related to immunocontraception, immune response has been shown to be heritable (Kean et al. 1994, Sarker et al. 1999). Unfortunately, predictions about the long-term, population-level evolutionary response to immunocontraceptive treatments are speculative at this time, with results likely to depend on several factors, including: the strength of the genetic predisposition to not respond to the fertility control vaccine; the heritability of the responsible gene or genes; the initial prevalence of that gene or genes; the number of mares treated with one or more doses of the vaccine; and the actual size of the genetically-interacting metapopulation of horses within which the vaccine treatment takes place. BLM is not aware of any studies that have quantified the heritability of a lack of response to immunocontraception (such as PZP vaccine or GonaCon-Equine) in horses or burros. At this time, there are no studies available from which one could make conclusions about the long-term effects of sustained and widespread immunocontraception treatments on population-wide immune function. Although a few, generally isolated, feral horse populations have been treated with high fractions of mares receiving PZP immunocontraception over long time periods (e.g., Assateague Island National Park, Cape Lookout National Seashore, Pryor Mountains Herd Management Area), no studies have tested for changes in immune competence in those areas. Relative to the large number of free-roaming feral horses in the western United States, immunocontraception has not been, and is not expected to be used in the type of widespread or prolonged manner that might be required to cause a detectable evolutionary response.

In summary, there are few uncertainties about the outcomes of the Proposed Action. The study is designed to determine whether or not individual vaccine-treated mares do, or do not, become infertile and for how long, over the course of the three-year study. There is good reason to quantify those effects and

test the duration of efficacy of the vaccine over three years, but the set of possible outcomes is clearly identified. The initial study conducted with a different formulation of the OGF vaccine required four doses to be effective, but the outcome was infertility, disruption of ovarian follicle development, and a cessation of estrus cycling (Appendix A). Those were the intended consequences, and those are the expected and desired consequences of the one-dose OGF vaccine formulation. The action is not controversial, in the sense that there is no scientifically-based reason to expect general outcomes of vaccination other than either vaccine success or failure (as defined above) in individual treated mares.

Impacts after Study Conclusion
There are potential impacts on wild horses after they are no longer included in the study, or after the study has concluded. If treatment with oocyte growth factor vaccine leads to long-term infertility, it may be of interest to determine whether there are effects on female foals born to treated mares. It is conceivable that a future study could monitor ovarian function in female offspring born to vaccine-treated mares, beyond the 3-year duration of the Proposed Action.

At the end of the study, animals could be placed in private care through adoption or sale with limitations, or could go to long-term care in an off-range pasture (ORP), as already analyzed in the gather decisions that led to their removal from the public range.

Impacts of Alternative 2 (No Action)
Under the No Action Alternative, no elements of the proposed study would affect wild horses at the NNCC. However, wild horses at NNCC would continue to be maintained, housed, fed, and trained at the NNCC, consistent with BLM policy and with the existing BLM-NNCC contract.

4.3 Cumulative Effects

The NEPA regulations define cumulative impacts as impacts on the environment that result from the incremental impact of the Proposed Action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency or person undertakes such actions (40 C.F.R. § 1508.7). Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. The cumulative impacts study area (CSA) for the purposes of evaluating cumulative impacts is limited to the NNCC, and specifically the wild horses that would be included in the Proposed Action.

According to the 1994 BLM *Guidelines for Assessing and Documenting Cumulative Impacts*, the cumulative analysis should be focused on those issues and resource values identified during scoping that are of major importance. Accordingly, the issues of major importance to be analyzed are limited to Wild Horses.

4.3.1 Past and Present Actions

4.3.1.1 Wild Horses

Management actions that have influenced the wild horses at the NNCC are primarily wild horse gathers, which led to the removal of those horses from the range and their designation as excess animals, as a result of previous BLM gather decisions. The Proposed Action Alternative would cause an incremental change in potentially preventing future reproduction for mares treated with the oocyte growth factor vaccine. However, under current management, mares that have been removed from the range and are placed in BLM long-term care facilities do not breed with stallions. Unless they go into private care, wild mares live exclusively with other mares or with gelded (infertile) males. In the context of over 45,000

wild horses living in some form of off-range holding, the loss of reproductive capacity for up to approximately 16 mares treated with the one-dose OGF vaccine would not represent a substantial change.

4.4 Reasonably Foreseeable Future Actions

4.4.1 Wild Horses

It is not expected that genetic health of any wild horse herd in the wild would be impacted by the Proposed Action Alternative, because the animals that would be included in the action would have already been removed from the public lands as excess animals, and would not be expected to be returned to the wild. Any future wild horse management action that could include returning mares from the proposed study back to the wild would be subject to NEPA compliance, following site-specific planning.

Various forms of fertility control can be used in future wild horse and burro herd management. These can help with the goals of maintaining herds at or near AML, reducing fertility rates, and reducing the frequency of gathers and removals. The WFRHBA of 1971 specifically provides for contraception and sterilization (16 U.S.C. 1333 § 3(b)(1)). An extensive body of peer-reviewed scientific literature details the expected impacts of various fertility control methods on wild horses and burros.

The effects of the one-dose oocyte growth factor vaccine may lead to short-term or long-term mare infertility, or to sterility. Regardless, any future BLM herd management actions using the one-dose OGF vaccine in on-range management would also require additional NEPA compliance. The results of the proposed study could help to inform BLM in future decisions about the potential use of the one-dose OGF vaccine. However, a few topics are worth mentioning in the context of reasonably foreseeable future actions.

Additional studies of the short-term and longer-term effects of the single-dose OGF vaccine could be warranted in the future. It is conceivable that the animals in the study could be observed further into the future, either as part of an additional study, or through non-experimental monitoring activities. If that occurs, BLM would ensure that any long-term (i.e., 10-year) study of the same animals is in compliance with NEPA. Although it is possible that the OGF vaccine could be used in a future field trial with wild, free-roaming horses on BLM-managed lands in the future, or as part of management activities, any such future action would be analyzed appropriately with site-specific planning with public involvement, and would not be part of the cumulative effects to the wild horses in the proposed action.

Fertility control that affects individual horses and burros does not prevent BLM from ensuring that there will be self-sustaining populations of wild horses and burros in single herd management areas (HMAs), in complexes of HMAs, and at regional scales of multiple HMAs and complexes. Under the WFRHBA of 1971, BLM is charged with maintaining self-reproducing populations of wild horses and burros. The NAS (2013) encouraged BLM to manage wild horses and burros at the spatial scale of "metapopulations" – that is, across multiple HMAs and complexes in a region. In fact, many HMAs have historical and ongoing genetic and demographic connections with other HMAs, and BLM routinely moves animals from one to another to influence local herd phenotypes and genotypes, and maintain high genetic diversity. Some HMAs could also be managed as non-reproducing, in whole or in part, depending on the specific circumstances and on a case-by-case basis. Thus, although fertility control vaccine-treated individuals may experience long-lasting effects, such as sterility, that does not of itself cause negative demographic or genetic impacts at the level of wild horse populations, which are the object of BLM management for decisions that address wild horse herd management.

Site-specific NEPA analyses for herds that are 'non-reproducing' in whole or in part should be considered in the context of this 'metapopulation' structure, where self-sustaining herds are not necessarily at the

scale of single HMAs. So long as the definition of what constitutes a self-sustaining population includes the larger set of HMAs that have past or ongoing demographic and genetic connections – as is recommended by the NAS 2013 report – it is clear that single HMAs could potentially be managed as nonreproducing in whole or in part while still allowing for a self-sustaining population of wild horses or burros at the broader spatial scale. Wild horses are not an endangered species (USFWS 2015), nor are they rare. Nearly 72,000 adult wild horses and over 16,000 adult wild burros roamed public lands as of March 1, 2019. Those numbers do not include at least 7,500 WH&B on US Forest Service lands, and at least 50,000 feral horses on tribal lands in the Western United States (Wallace et al. 2017, Beever et al. 2018).

Because any future herd management actions that include long-lasting mare contraception, including sterilization, via oocyte growth factor vaccine injection would likely require capturing, handling, and some form of marking, the risks and costs associated with animal capture and handling may be comparable to those of gathering for removal, but would be anticipated to lead to lower subsequent gather, adoption and long-term holding costs and a reduction in excess wild horses that have to be removed from the range. As noted previously, treating mares with a fertility control vaccine may lead to those mares having a longer lifespan. If this were to happen in a herd of horses living on the range, then, changes in lifespan and decreased foaling rates could combine to cause changes in overall age structure in a treated herd (i.e., Turner and Kirkpatrick 2002, Roelle et al. 2010), with a greater prevalence of older mares in the herd (Gross 2000).

If the oocyte growth factor vaccine leads to successful outcomes, in terms of causing long-lasting contraceptive effects, then it is reasonable to expect that BLM might develop guidelines for oocyte growth factor vaccine use in the future, similar to those for other immunocontraceptive vaccines. Existing, non-binding guidelines for fertility vaccine use in BLM wild horse herd management (BLM IM 2009-090) suggest that herds selected for fertility control vaccine use should have background annual growth rates over 5%, have a herd size over 50 animals, and have a target rate of treatment of between 50% and 90% of female wild horses or burros. Guidelines suggest that treated mares should be identifiable via a visible freeze brand or individual color markings, so that their vaccination history is known, and that follow-up population surveys should be used to determine the realized annual growth rate in herds treated with fertility control vaccines.

5.0 Monitoring and Mitigation Measures

The BLM COR assigned to the NNCC contract would be responsible for ensuring contract personnel abide by the contract specifications and the CAWP (Appendix C). Animal care will also be in keeping with protocols approved by the NWRC IACUC (Appendix B). Out of an abundance of caution, the oocyte growth factor vaccine will not be handled by female during this study. Ongoing monitoring of animal health would continue. BLM would continue to contract with an attending veterinarian, to be available for animal care, as needed. NWRC researchers would monitor the immune response and pregnancy status of treated and untreated mares.

6.0 List of Preparers

The following list identifies the interdisciplinary team member's area of responsibility.

Name	Title	Area of Responsibility
Ruth Thompson	Wild Horse Specialist	Project Lead/Wild Horses

Paul Griffin	Research Coordinator	Study Review
David Pritchett	Planning/NEPA/CADR Program Lead	Study Review

7.0 Consultation and Coordination

The NWRC proposal was reviewed by the BLM WHB program research advisory team. The team includes four BLM employees, and one USDA veterinarian not affiliated with NWRC, and has input from the WHB Advisory Board member whose purview is research.

8.0 Public Involvement

A preliminary environmental assessment was made available to interested individuals, agencies, and groups for a 15-day public review and comment period that opened on December 5, 2019 and closed on December 20, 2019 . Forty four comments were received from individuals, organizations, and county or state government agencies. Many of these comments contained overlapping issues/ concerns which were consolidated into 61 distinct topics. Below is a detailed summary of the comments received, BLM's responses, and how BLM used these comments in preparing the final environmental assessment. Comments and Responses can be found in Appendix E.

9.0 Appendices

Appendix A – USDA Research Proposal
Appendix B – USDA Animal Care and Use Protocol
Appendix C – Comprehensive Animal Welfare Program
Appendix D – Literature Cited
Appendix E – Comments and Responses