United States Department of the Interior
Bureau of Land Management

Preliminary Environmental Assessment
DOI-BLM-NV-0000-2020-0001-EA

Oocyte Growth Factor Vaccine Study

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1.0 Purpose and Need for Action

1.1 Introduction

This environmental assessment (EA) has been prepared to disclose and analyze the environmental consequences 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-captured wild horses.

This EA analyzes the potential impacts that could result with the implementation of the Proposed Action or a No-Action alternative to the Proposed Action. 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

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." One of the conclusions in the NAS Report was that, in some situations for wild horse and burro management, “A single treatment that induces lifetime infertility could be preferable…” Since 2013, BLM has funded development and testing of various methods that could lead to long-lasting fertility control requiring a minimum number of wild horse or wild burro handling occasions.

Since the passage of the Wild Free-Roaming Horses and Burros Act (WFRHBA) of 1971, BLM has refined its understanding of how to manage wild horse and burro population levels. By law, BLM is required to control any overpopulation of excess animals. The program goals have always been to establish and maintain a “thriving natural ecological balance” which requires identifying the Appropriate Management Level (AML) for individual herds. In the past two decades, goals have also included applying contraceptive treatments to achieve and maintain wild horse population within the established AML, so as to manage for healthy wild horses 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. 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 BLM policy

Across the 10 western states where BLM administers wild horses and burros, these animals tend to have exceptionally high reproductive and survival rates. As a result, wild horse and burro herds have continued to grow at high rates. While there are several fertility control vaccines available for BLM to use (PZP Zonastat-H, PZP-22 vaccine pellets, and GonaCon), those vaccines have limited duration of effect, especially if only one dose of the vaccine is given to the mare (Rutberg et al. 2017, Baker et al. 2018). To cause long-lasting physiological effects, existing fertility control vaccines require repeated capture and vaccine applications to.

BLM’s Use of Contraception in Wild Horse Management

BLM has identified fertility control as a method that could be used to protect rangeland ecosystem health and to reduce the frequency of wild horse and wild burro gathers and removals. Expanding the use of population growth suppression to slow population growth rates and reduce the number of animals

removed from the range is a BLM priority. The WFRHBA of 1971 specifically provides for sterilization (section 3.b.1). No finding of excess animals is required for BLM to pursue contraception in wild horses or wild burros.

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). Contraception by itself does not remove excess horses from an HMA's population. Instead, successful contraception reduces future reproduction. So if a wild horse population is currently in excess of 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 of management value to BLM. The benefit of contraception in wild horse management results because successful contraception would be expected to reduce the frequency of horse gather activities, as well as wild horse management costs to taxpayers. 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. Bartholow (2007) also concluded that contraceptive treatment would likely reduce the number of horses that must be removed in total, with associated cost reductions in the number of private placements and total holding costs. There is additional motivation to identify long-lasting contraceptive methods: population suppression becomes more cost-effective if fertility control is long-lasting (Hobbs et al. 2000). 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, do not of themselves 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 site-specific analysis, as informed by scientific information available at that time.

Two of the three fertility control treatments that the NAS (2013) identified as being the "most promising" for immediate use were the porcine zona pellucida (PZP) and gonadotropin releasing hormone (GnRH) fertility control vaccines. Those 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, development for use in wild horse management.

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 resulting biosecurity measures could lead to a reduced availability of pig ovaries for vaccine producers, or even an outright ban on the injection of pig-derived products into any species that might impact livestock. 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 vaccine is effective, then it could cause short-term infertility, and may cause or longer-term sterility in treated mares. Such a one-dose fertility control vaccine would 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. A previous 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).

Fertility control vaccines (also known as (immunocontraceptives) 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 in a small number of wild horses already removed from the range as excess, 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. A previously tested version of the vaccine caused contraception for at least 2 years, but it used a weak vaccine adjuvant that required multiple doses to be effective.

This action is needed in order to determine whether the one-dose oocyte growth factor vaccine could be a reliable, 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 Wild Free-Roaming Horses and Burros Act of 1971 (WFRHBA)[1] and 43 CFR 46.210 (e).

1.4 Land Use Plan Conformance

The Proposed Action is in conformance with the Carson City Consolidated RMP (2001), Even though it is not specifically provided for, and because it is clearly consistent with the following RMP decisions (objectives, terms, and conditions):

- Standard Operating Procedures: # 3 "*The range of horse numbers will be designed to maximize the interval between removals (3-5 years). Also 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 is in conformance with the WFRHBA of 1971 (as amended), applicable regulations at 43 CFR § 4700, and BLM policies. The Action Alternative is also consistent with 43 CFR 46.210, and does not meet any extraordinary circumstance that would require further NEPA review. BLM Nevada has chosen to analyze the Action Alternative in an EA to allow for additional public input after publication of the preliminary EA.

[1] The Interior Board of Land Appeals (IBLA) 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.'"

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, wild horses would be housed and maintained at the Northern Nevada Correctional Center (NNCC). BLM contracts with NNCC for the maintenance and care of wild horses.

2.2.2 Proposed Action

The Proposed Action would include a study designed to test the efficacy of a modified fertility control vaccine in wild mares, over a three-year period. This study research is needed to improve the understanding of the effects of a 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.

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 16 mares with the fertility control vaccine;
- Non-treatment of 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 2 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. 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, 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.
- BLM contract Veterinarian, 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 (Washington Office Instruction Memorandum 2015-070.

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.

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 considered in detail 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. Results of the most recent trials for both SpayVac and the nominally long-lasting PZP vaccine pellet formulations were not favorable, 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). This alternative was not considered in detail 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 continue or increase the use of 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 including the following. 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. 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. 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. There are public lands approximately a half mile east of the areas on the NNCC where animals are maintained and handled.

There is no public access to the areas of the NNCC where the study would take place. Although the public can come onto NNCC grounds for scheduled adoption events, those are in an area that is distinct from the area where horses would be housed, cared for, 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.

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 never be handled by human females associated in any way with the Proposed Action. 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). 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).

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. Lack of estrus behaviors has also been observed in mares vaccinated with a different fertility control vaccine, GonaCon (Ransom et al. 2014b); in that study, 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.

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 CFR 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 excess horses from the range. 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 do not reproduce. 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 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 analyzed appropriately, as per NEPA, following site-specific planning with public involvement.

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 section 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.

Whether the effects of the one-dose oocyte growth factor vaccine lead to long-term mare infertility, or to sterility, any future BLM herd management actions that would consider use of the vaccine would require additional NEPA analysis. However, a few topics are worth mentioning in the context of reasonably foreseeable future actions.

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 never be handled by women associated with this project. 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

This Preliminary EA is being sent to a list of tribes, state government agencies, non-governmental organizations, and individuals that have expressed interest in WHB management in the past. The Preliminary EA will be made available to the public for a 15-day period of public review. BLM will consider and respond to public comments as part of any final EA.

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