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Environmental Assessment
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Wild Mare Fertility Control Research

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1.0 Purpose and Need for Action

1.1 Introduction

The Bureau of Land Management (BLM) has prepared this environmental assessment (EA) to analyze and disclose the environmental impacts of three proposed research studies that would test the contraceptive effects of several potentially long-lasting fertility control treatments for wild mares. The BLM, in cooperation with researchers, would have a role in conducting the research.

In the first study (study A) of the Proposed Action, an initial 8-month test of four oocyte growth factor (OGF) vaccine formulations would be used to identify the two formulations that lead to the greatest immune response in mares. The contraceptive effects of those two OGF vaccine formulations would then be tested during a 3-year trial. The second study (Study B) would test the contraceptive effects of the SpayVac formulation of PZP vaccine for up to 5 years. Studies A and B would both use captive mares and stallions that were previously gathered and removed from the range under 16 U.S.C. 1333(b). In the third study (study C), wild mares would be gathered, treated with a flexible intrauterine device (IUD) design, known as iUPOD, and then returned to the range. These actions would be consistent with management actions authorized in the Calico Complex Gather Plan (DOI-BLM-NV-W030-2019-0019-EA) but would be structured as an experiment that would allow outcome comparisons between IUD-treated mares and fertility control vaccine-treated mares. In study C, the free-roaming mares would be observed to document contraceptive and behavioral effects of the IUD treatment over 4 years. For additional details about the Proposed Action, see section 2.2.2.

This EA analyzes the potential impacts that could result from the implementation of the Proposed Action.[1] The Proposed Action includes all three studies, but the impacts of each study are analyzed separately. BLM also considered other alternatives but has dismissed them from detailed analysis as they do not fulfill the identified purpose and need. 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, as amended, 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 wild horses and burros in a manner that is "designed to achieve and maintain a thriving natural ecological balance on the public lands." *Id*.

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.* § 1333(b)(2). While

[1] The Proposed Action involves studying the efficacy of certain fertility vaccines and a flexible type of IUD on long-term fertility rates in wild mares. Studies of this kind, which are conducted by various federal agencies, are typically categorically excluded from detailed environmental analysis. For example, the Animal and Plant Health Inspection Service routinely categorically excludes vaccination trials on groups of animals at controlled sites and research evaluating wildlife management products or tools (7 C.F.R. § 372.5(c)(2)(i)), and the Proposed Action being analyzed in this EA falls under the Department of the Interior's categorical exclusion for nondestructive data collection, inventory, study, research, and monitoring activities at 43 C.F.R. § 46.210(e). Nevertheless, the BLM has prepared this EA to better inform the agency and the public about Proposed Action's environmental impacts, particularly the potential of any of the vaccines or the IUD to have long-lasting fertility effects on wild mares.

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.* § 1333(a); § 1333(b)(1).

There could be long-term benefits to federal wild horse and burro management if there are longer-lasting fertility control methods for mares than those currently available, and which require only a single handling occasion to be administered. In its 2020 report to the U.S. Congress about how to achieve a sustainable WHB program, the BLM indicated that it would seek to continue research into improving long-term fertility control treatments and humane permanent sterilization options. The BLM's 2021 wild horse and burro program strategic research plan identifies the development and testing of long-lasting fertility control methods for mares to be the agency's highest research priority with respect to horses and burros.

Among other motivations for the identification of longer-lasting fertility control methods, such methods could ultimately reduce the number of animals that would need to be gathered, removed from the public lands, and cared for at off-range pastures and corrals (BLM 2020, 2021a). BLM has determined that the high end of AML for wild horses and burros on the range is 26,785. That number is the sum of AML values for 177 herd management areas (HMAs). However, as of March 1, 2022, there were estimated to be over 82,000 BLM-managed wild horses and burros on the range (https://www.blm.gov/whb). By that measure, the population on the range exceeds AML by more than 55,000 animals, or more than double the number of wild horses and burros that the range can sustain in a thriving natural ecological balance. While wild horses and burros can undoubtedly play ecological roles that most would interpret as beneficial when they are found at densities within AML, 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." In addition to those animals on the range, there are currently over 50,000 excess wild horses and burros permanently removed from the public lands that BLM houses and cares for in short- and long-term care facilities, at great taxpayer expense. The limited funding and space available for the care of additional excess animals in short- and long-term care facilities impedes BLM's ability to manage wild horses and burros on public lands for a thriving natural ecological balance.

Wild horses and burros tend to have reproductive and survival rates that can cause high population growth rates compared to other free-roaming ungulates. The agency's focus on mare fertility control, and not stallion fertility control, is rooted in horse social behaviors and associated demographic modeling. A small number of fertile stallions can impregnate a larger number of fertile mares, because multiple adult mares typically consort with a single stallion, and because fertile mares have estrus cycles every three weeks or so throughout the breeding season until they become pregnant. There is a linear relationship between mare contraception and herd growth rate, in that every mare that is effectively contracepted represents a proportional reduction in the number of foals the following year. In contrast, the number of stallions contracepted does not start to markedly reduce herd growth rates or the number of foals expected until a very high fraction of stallions are all infertile (Garrott and Siniff 1991). Sustainedly high percentages of stallions would be required to be infertile to cause substantially reduced mare fertility rates over time (Garrott and Siniff 1991). The high fraction of stallions that would need to be infertile, and the high frequency of gathers needed to treat young stallions as they mature are noted in the 2021 WHB program strategic research plan (BLM 2021a) as two reasons why it is a higher priority instead to develop and test humane, longer-lasting mare fertility control methods for wild mares, preferably which can achieve that result from a single handling occasion.

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 wild horse and burro management situations. With regards to the duration of a fertility treatment's efficacy, that 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."

There is currently no available fertility control vaccine for wild horse mares from which one dose reliably leads to substantial effects lasting longer than approximately two years (Rutberg et al. 2017, Baker et al. 2018, Carey et al. 2019). BLM has attempted to address both the high population growth rate of wild horses and burros and their overpopulation on the range by using a variety of management actions, including periodic gathers and removals, sex-ratio adjustments, and temporary fertility control vaccines such as porcine zona pellucida (PZP) Zonastat-H (EPA 2012), PZP-22 vaccine pellets (Rutberg et al. 2017), and the GonaCon vaccine (EPA 2013). However, given the limitations of those methods, historical and current logistical constraints, and funding levels that limit the frequency of gathers and number of animals that can be removed or treated with fertility controls, these methods have not proven effective at substantially reducing the population size or annual growth rates of most wild horse and burro herds in the long-term. Gathers and removals do not, by themselves, limit the ability of wild horses and burros to reproduce. To cause long-lasting contraceptive effects, existing fertility control vaccines require repeated booster applications. The processes necessary to administer repeated vaccine applications that are separated in time by weeks or months can cause repeated stress to the animals. Re-vaccination can require recapturing animals and/or holding animals in captivity. Capture and vaccination can be difficult for BLM to repeatedly perform, due to topography, HMA size, skittishness of the horses, and other factors such as funding availability, logistical capacity to gather the animals, and personnel availability.

Since the NAS published its 2013 report, BLM has funded the development and testing of new contraceptive methods that could lead to long-lasting fertility control.[2] BLM's goal has been to develop and use humane, safe 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. To ensure self-sustaining populations of wild horses and burros on the public lands, the agency would not seek to cause such high frequencies of contraception or sterility as to prevent the long-term presence of these federally protected animals on the public lands where they belong, though some level of permanent infertility within the population may be desirable or acceptable in achieving an overall level of reproduction that is more sustainable in the long-term.

In November 2021, the BLM solicited proposals for research into longer-lasting mare fertility control methods. The BLM released 'notice of funding opportunity' (NOFO) number L22AS00069 (BLM 2021b), to which individuals, non-profit organizations, universities, local and state agencies, and other qualified institutions were eligible to respond. The maximum duration of funding allowed through that funding opportunity was 5 years, which is typical for federal financial assistance agreements. In parallel,

[2] These include, but are not limited to testing the safety and effects of: booster doses of GonaCon vaccine in feral mares; flexible silicone intrauterine devices (IUDs), new formulations of PZP vaccine, and tubal ligation in domestic mares; and initial formulations of oocyte growth factor vaccines in domestic and wild mares.

the BLM released a virtually identical 'request for proposals' (RFP) that federal agencies were eligible to respond to (link available via the BLM WHB Research web page: https://www.blm.gov/programs/wild-horse-and-burro/herd-management/science-and-research). In keeping with guidelines specified in that NOFO and RFP, the research projects considered in the Proposed Action were reviewed by a panel of external subject matter experts, and by an internal, interagency panel including some BLM research advisory team personnel (BLM 2021a). The research projects included for consideration in the Proposed Action are among those that BLM determined to be most promising, based on external and internal recommendations, available funding levels and constraints in Congressionally appropriated fiscal year 2022 funding and requested BLM budgets for future years.

The Proposed Action in this EA involves three research studies that would test the effects and utility of various fertility control methods in wild mares. The research studies that compose the Proposed Action are designed to determine whether the selected methods could provide reliable, long-lasting fertility control in wild mares. Preliminary formulations or applications of the proposed methods have already been shown to be safe in domestic mares, and in some cases also in wild mares. If one or more methods tested in the proposed research studies prove effective at providing long-term contraception, those methods could be considered for use in future BLM wild horse and burro herd management actions. However, the research contemplated in the Proposed Action would not determine whether the methods considered would or would not be used in any future BLM management action. The BLM would decide whether to implement any of the long-term contraception methods as part of future BLM management actions through a separate decision-making process that complies with applicable laws, including the National Environmental Policy Act (NEPA).

Contraception Methods in Wild Horse Management

In recent years, the BLM has increased its use of fertility control in WHB management to slow population growth rates, reduce the overpopulation of wild horses on public lands, decrease the number of animals that the BLM must gather and remove from the range, and ultimately protect rangeland ecosystem health and help to achieve a thriving natural ecological balance. The U.S. Congress specifically contemplated the use of long-term fertility control as a tool for wild horse and burro management when it passed the WFRHBA. 16 U.S.C. § 1333(b). Fertility control may include temporary contraception of individual animals or permanent sterilization. Repeated doses of available fertility control vaccines, although nominally reversible, may cause lifetime contraception. Although fertility control treatments on individual wild horses may be associated with some potential physiological, behavioral, demographic, and genetic effects, the 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 fundamentally alter the treated animals' inherently rebellious and feisty nature and their defiance of humans; do not prevent overall maintenance of a self-sustaining population at the broader scale of wild horse herds or metapopulations; 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).

When used with other techniques, contraception can be a cost-effective and humane treatment to slow increases in wild horse populations and reduce horse population size (Bartholow 2004, de Seve and Boyles-Griffin 2013, Fonner and Bohara 2017). Bartholow (2007) concluded that the application of 2- or 3-year duration 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.

A number of humane, safe, effective contraceptive methods exist and have been tested in domestic mares, including but not limited to the use of fertility control vaccines (also called immunocontraceptives), flexible IUDs, and humane, minimally-invasive sterilization techniques. Each method has its advantages and limitations. Any fertility control vaccines, flexible intrauterine devices, and minimally-invasive physical sterilization methods that might be used in BLM's routine WHB management in the future would meet guidelines for safety to mares and the environment (i.e., EPA 2009, 2012, 2013, 2020). What follows are brief, general descriptions of immunocontraceptive vaccines and flexible intrauterine devices for horses. For a more complete literature review of those and other horse fertility control methods, see Appendix C. Analysis of expected impacts of the specific projects included in the Proposed Action is presented in section 4.2.

Vaccines – Vaccines are intended to foster an immune response against antigen molecules. Vaccines typically also include adjuvants, which are additional compounds that heighten immune response to the antigen. Many adjuvants intensify the body's reaction to the antigen by causing temporary or localized effects such as slight inflammation at the injection site or mild fever, in a way that can enhance innate immune system and adaptive immune system responses. In this way, antigens can magnify or prolong the immune system's recognition of the antigen as a target for antibody production. Immune inhibition of the antigens in fertility control vaccines is intended to reduce fertility. Two of the three fertility control treatments that the NAS identified in 2013 as being the "most promising" for immediate use were fertility control vaccines that have either porcine zona pellucida (PZP) proteins or gonadotropin releasing hormone (GnRH) as antigens. The PZP or GnRH vaccines were deemed promising by NAS in 2013 partly because of the ease of their delivery method by injection, their availability, their relative efficacy, their safety in the environment, and evidence that identified physiological side effects outside of the reproductive system are limited. Single doses of the current formulations of PZP and GnRH fertility control vaccines available for use in wild mares cause contraceptive effects that may last only two years or less (Rutberg et al. 2017, Baker et al. 2018, Carey et al. 2019).

Fertility control vaccines that confer long-lasting effects from a single injected dose would be useful in wild horse management. New vaccines in this context could include new antigens, new adjuvants, or different formulations or delivery mechanisms. One formulation of PZP vaccine, in which the PZP molecules are encapsulated in liposomes that may act as an antigen or prolong the time period when antigen is presented to the body's immune system (Bechert et al. 2013), is known by the trade name SpayVac. Previous studies testing the long-term effectiveness of SpayVac in mares have had inconsistent results. SpayVac vaccine is now produced by a different company and in a different laboratory than when it was made for the most recent BLM-funded trial, during which there were results with undesirably low contraceptive efficacy (see section 2.2.2.B). One reason why it may be prudent to test fertility control vaccines with different antigens is the small, but measurable risk that the availability of vaccines made from native PZP could be limited in the future, if African swine fever reaches the United States. In that circumstance, it could be conceivable that the supply of pig ovaries essential to the development of PZP could be affected, or that there could be restrictions on the movements of swine-derived tissues. Vaccines that cause an immune response to oocyte growth factor (OGF) antigens did not exist when the NAS reviewed available fertility control methods in 2013. Vaccines against two oocyte growth factors, GDF9 and BMP15, have been tested preliminarily in domestic mares, leading to safe, contraceptive results (Davis et al. 2018). Testing the effectiveness of SpayVac vaccine or improved OGF vaccine formulations (i.e., with different adjuvants) in wild mares could provide efficacy results that could inform their potential use in future wild horse management. The research proposals addressing these two vaccines are available in Appendices D and E.

Flexible Intrauterine Devices (IUDs) – Flexible IUDs are considered a temporary fertility control method that does not generally cause future sterility (Daels and Hughes 1995). Because placement of an IUD could disturb an established pregnancy, only non-pregnant wild mares are candidates to receive an IUD.

A veterinarian must screen mares for pregnancy status before IUD placement. The NAS reported that use of IUDs would have merit but suggested in 2013 that research should study whether IUDs cause uterine inflammation, and record how well IUDs stay in mares that live and breed with fertile stallions. Since 2013, researchers have tested several flexible IUD designs in domestic and feral mares. Following good results about retention rates, uterine health effects, and contraceptive effects for a flexible Y-shaped silicone IUD design (Holyoak et al. 2021, Lyman et al. 2022), BLM has started to use those IUDs to reduce mare fertility on the range (see DOI-BLM-UT-W020-2020-0002-EA, and DOI-BLM-WY-D040-2020-0005-EA). The model of flexible IUD contemplated for study in the Proposed Action is a different IUD model known as the iUPOD IUD, and is discussed in more detail in section 2.2.2.C of this EA. It has been shown effective at preventing pregnancy and prolonging estrus cycles in breeding and non-breeding domestic mares (Gradil et al. 2019, Hoopes et al. 2021, Joonè et al. 2021, Gradil et al. 2021). The iUPOD IUD has not yet been used in BLM-managed wild mares. The research proposal related to iUPOD IUDs is available in Appendix F.

1.3 Purpose and Need for Action

The purpose of the Proposed Action is to test the efficacy of three fertility control methods in wild mares: SpayVac PZP vaccine, OGF vaccine formulations, and the iUPOD IUD. BLM would test those methods by funding agreements to research institutions that would conduct research studies, allowing BLM-managed wild horses to be included in the studies, and providing BLM resources, BLM-administered corral and/ or pasture space, and BLM personnel time in support of the necessary actions. Specific actions that each of the three studies would entail are described in this EA and associated Appendices.

This action is needed to determine whether there are additional fertility control methods for wild mares that are humane, safe, reliable, and long-lasting, and that have the potential to help the BLM achieve thriving natural ecological balance on public lands through future wild horse management actions. As already noted, future management actions would be subject to separate decision-making processes by BLM. The need for this action was also explained in discussions about the motivation for finding improved longer-lasting fertility control methods in the BLM's 2020 report to the U.S. Congress, which noted that, "...research could lead to breakthroughs in longer-lasting fertility control and sterilization methods, which could significantly reduce wild horse and burro herd growth rates and out-year management costs" (BLM 2020; p. 22, 'Research'). Similarly, the need for this type of action led the BLM to highlight that the "...highest priority research topic remains the development of safe, practical, and effective, long-lasting fertility control methods for mares," in the BLM 2021 WHB program strategic research plan (BLM 2021a, p. 1).

1.4 Land Use Plan Conformance

The OGF vaccine research project (Study A) and the SpayVac vaccine research project (Study B) would involve wild mares previously gathered and removed from public lands and that reside at the Northern Nevada Correctional Center (NNCC), a state of Nevada facility. The wild mares that would be involved in both studies will not be returned to federal public lands. It is therefore unnecessary for the OGF vaccine research project and the SpayVac vaccine research project to conform to a specific land use plan.

By comparison, the iUPOD IUD research project (Study C) would include wild mares gathered from the Calico Complex. These mares would undergo pregnancy screening, marking, IUD treatment, and GPS radio collaring at a holding facility such as, but not necessarily limited to, the NNCC or Palomino Valley Wild Horse and Burro Center (PVC). They would then be released back onto public lands in the Calico Complex for the duration of the study. Conduct of the iUPOD IUD research study at the Calico Complex would be in conformance with the *Black Rock Desert-High Rock Canyon Emigrant Trails National Conservation Area (NCA) and Associated Wilderness, and other Contiguous Lands in Nevada Resource Management Plan* (BRRMP), July 2004 and the *Winnemucca District Resource Management Plan* (WDRMP), May 2015. In the WDRMP (2015), Action WHB 5.3 calls for fertility control to slow

population growth rates. In addition, application of IUDs and GPS radio collars is consistent with the 2021 BLM Winnemucca District Office management decision for the Calico Complex, as analyzed in DOI-BLM-NV-W030-2019-0019-EA, which is incorporated by reference in the analyses of this EA. EA section 2.2.2.C, below, and Appendix F note how study C would use methods approved in that decision, but with data collection structured as an experiment to allow for foaling rate, uterine health, and behavioral outcome comparisons between IUD-treated mares and fertility control vaccine-treated mares.

1.5 Relationship to Laws, Regulations, and Other Plans

Statutes and Regulations

The Proposed Action has been designed to conform with Federal laws, 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). 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.

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.

(a) All management activities shall be at the minimal feasible level…

(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.

The Proposed Action includes testing to determine whether three fertility control methods cause short-term contraception, long-term-contraception, or sterilization, in federally-protected wild horses. For the OGF vaccine and SpayVac vaccine studies contemplated in the Proposed Action, the wild horses that will take part in those studies have been previously determined to be excess animals and will have been already permanently removed from the range. In the case of the IUD study, the horses to be screened for pregnancy and treated with IUDs or GonaCon vaccine then returned to the range will have already been determined to be eligible for temporarily removal for the purpose of fertility control treatment. BLM has supported and aided past research in which federally-protected wild horses have been used, and that tested a number of other temporary and permanent fertility control methods, including PZP vaccine formulations, GonaCon vaccine, IUDs, hormonal treatments, castration, and vasectomy.

2. ***Federal Land Policy and Management Act*** (Pub. L. 94-579), as amended

The Proposed Action studies fertility control methods 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, Federal Regulations*** (43 C.F.R. Part 4700)
The Proposed Action is consistent with 43 CFR Part 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 the selected fertility control methods could lead to long-term contraceptive effects in wild horse mares. Currently available fertility control vaccines require more than one dose to have long-lasting effects. Therefore, if any of the methods studied are effective in causing long-term infertility, their 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, but they do provide guidance to help inform BLM management. The Proposed Action is consistent with handbook H-4700-1 (BLM 2010) 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 2005 WHB strategic research plan has been updated, and development and testing of long-lasting mare fertility control was identified as the highest priority for research (BLM 2021a). The Research Advisory Team was a part of the review process for fertility control research proposals received in response to NOFO L22AS00069 and the accompanying RFP. If successful, one or more of the methods in the Proposed Action may be a form of mare fertility control that lasts three to five years, or longer. The Proposed Action includes the testing of OGF fertility control vaccine formulations, of SpayVac PZP vaccine, and of an IUD, any of which could be responsive to current wild horse management needs, in the form of long-lasting fertility control methods that require only one handling occasion.

5. ***Comprehensive Animal Welfare Program*** (BLM IM 2021-002)
The Proposed Action is consistent with this policy. Animals in the study will be maintained, cared for and handled in compliance with the BLM Comprehensive Animal Welfare Program (Appendix B).

6. ***Other Regulatory Oversight***
The Food and Drug Administration (FDA) has general regulatory authority over the licensing of drugs and devices that are used in domestic horses. Such drugs and veterinary devices may also be used in feral horses, insofar as 43 CFR 4700.0-5(e) defines humane treatment with respect to accepted veterinary practices. However, most substances and devices that are used as contraceptives to control populations of feral horses and burros are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) rather than regulated as animal drugs or veterinary devices by the FDA. This would include application of immunocontraceptive vaccine formulations, such as for the OGF vaccine study and the SpayVac study in the Proposed Action, or use of flexible IUDs for the purposes of fertility control (i.e., EPA 2020). It is a requirement of the BLM that the researchers comply with all applicable requirements for contraceptive applications, including any necessary reporting requirements to regulatory agencies.

Prior to their participation in any work with horses that is outside the scope of the BLM's more typical management activities, investigators are required to provide the BLM with proof of Animal Care and Use Protocols (ACUP; Appendix I) that are approved by their respective Institutional Animal Care and Use Committee (IACUC).

1.6 Decision to be Made

The authorized officer will determine whether to authorize one or more of the research studies described in the Proposed Action. The authorized officer's decision is limited to whether to fund and conduct the studies within the Proposed Action, including all the associated BLM agency support that would entail. The Proposed Action includes three studies, but the authorized officer would have the latitude to decide to fund and conduct only one, only two, or all three studies. The decision would not authorize or set precedent for the use of any particular fertility control method in any future BLM wild horse and burro herd management actions, though preliminary or final results of the studies in the Proposed Action could inform future agency decision making. Any future decision by BLM to utilize any of the fertility control methods analyzed in this EA would be subject to future decision-making processes.

1.7 Scoping and Identification of Issues

The following issues were identified as a result of internal scoping and based on comments received by the BLM Nevada state office in response to DOI-BLM-NV-0000-2020-0001-EA, which was a study that analyzed a similar research project using a different formulation of OGF vaccines.

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

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

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 – Authorize one or more of the following three wild mare fertility control studies:
  - A. **Oocyte Growth Factor vaccine study** to assess long-lasting effects of different adjuvant formulations in a pen trial
  - B. **SpayVac vaccine study**, to assess long-lasting effects of a single dose in a pen trial
  - C. **iUPOD IUD study** to assess contraceptive effectiveness of that IUD on the range
- Alternative 2: No Action — Do not authorize any of the proposed studies

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, the No Action Alternative 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

Animals in the oocyte growth factor study (study A) or the SpayVac study (study B) would be selected from animals that will have already been permanently removed from the public lands as excess wild horses. In studies A and B, selected animals would be housed and maintained at the Northern Nevada Correctional Center (NNCC); the duration of time they spend at NNCC may be longer if they are enrolled in a study than it might have been if the BLM does not authorize the study. After their involvement with a study is over, those animals will continue to be cared for at the NNCC until they are adopted or sold according to existing BLM policy, or are moved to a different location for BLM care. For study C, participating mares would be selected from mares that are gathered pursuant to the Calico Complex wild horse decision record issued on July 28, 2021 (DOI-BLM-NV-W030-2019-0019-EA), which authorizes gathers, removals, pregnancy screening, return to the range of mares treated with fertility control by means of IUD or vaccine, and monitoring with GPS collars. Mares that are used in study C would be drawn from gathered mares that, pursuant to the July 28, 2021 decision, would otherwise be treated with an IUD or GonaCon vaccine prior to their release back into the Calico Complex.

All routine wild horse maintenance and care will follow the BLM's Comprehensive Animal Welfare Program (Appendix B). The BLM wild horse and burro program system (WHBPS) is the database in which the agency records and stores retrievable information about individual captive wild horses, such as HMA of origin, signalment, freeze brand, RFID chip number, fertility control treatment history, health records, and transportation history. All of this information for any given captive wild horse in the BLM's care can be provided to potential adopters.

2.2.2 Proposed Action

The Proposed Action would include up to three studies designed to test the efficacy of several fertility control methods in wild mares. These research studies are needed to improve the understanding of the efficacy of these fertility control treatments, at least one of which may prove to be a long-lasting fertility control method for wild horse mares. The BLM received proposals to conduct these studies in response to NOFO L22AS00069 or the parallel RFP. The actions associated with each of the three individual studies are explained below, however, certain aspects and the specific timing of the studies could change based on logistical and administrative factors.

2.2.2.A. **Oocyte Growth Factor (OGF) vaccine study (Study A)**

The proposal for research study A is titled "Identification of an Appropriate Single-Dose Long-Lasting Adjuvant and Related Efficacy of Oocyte Growth Factor Vaccine." The body of the proposal is included in Appendix D.

OGF vaccines are in a category that have had some preliminary contraceptive effectiveness and safety. A four-injection version of on OGF vaccine that would be used in this research has already been tested on domestic mares and appeared safe and successful (Davis et al. 2018). The motivation for study A is to identify whether a prolonged immune response to OGF proteins can be stimulated by a single injection of an OGF vaccine, formulated by one of four potential adjuvants. The BLM has not yet used any OGF vaccine in herd management on the range. In principle, an OGF vaccine could have some of the same advantages that have been identified in PZP and GonaCon vaccines, including that because they work by causing an immune response in treated animals, there is no risk of hormones or toxins spreading into the food chain. The study would be responsive to the search for a long-lasting, "…single treatment that induces lifetime infertility…" as was alluded to by the 2013 NAS report, and which has been identified as a priority by the BLM (2020, 2021a). The preliminary OGF vaccine formulation that was tested in domestic mares (Davis et al. 2018) used four doses of vaccine formulated with the Montanide Pet Gel A

adjuvant (Seppic SA, Paris, France; Deville et al. 2011). A four-dose regime is not practicable for use in free-roaming WHB. More recently, the BLM has supported studies of a single OGF vaccine formulation that used the Adjuvac adjuvant and in which the OGF antigens were encapsulated in phospholipid bilayer molecules known as liposomes (DOI-BLM-NV-0000-2020-0001-EA). Liposome molecules are also a feature of the SpayVac vaccine (Bechert et al. 2013). Preliminary results from that study in DOI-BLM-NV-0000-2020-0001-EA indicate that formulation was not successful in causing sustained immune response to OGF proteins from a single dose. In contrast to the study in DOI-BLM-NV-0000-2020-0001-EA, Study A as contemplated here would test four different OGF vaccine formulations.

Specific aim 1 of the proposed research would test the immunogenicity of four formulations of OGF vaccine, which would differ in formulation only in terms of the choice of adjuvant. The OGF vaccine formulations would all 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 D). 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. Each vaccine dose would include 500 µg of this conjugated carrier-protein / antigen molecule.

The experimental aspect of specific aim 1 of the study is variation in adjuvants, in the vaccine preparations. OGF vaccines would be prepared with four different adjuvants, as described in specific aim 1 of the proposal (Appendix D). 48 non-pregnant mares would be included for treatment in specific aim 1. Each mare would receive one dose, randomly assigned to be one of the four formulations, for a total of 12 mares per treatment type. Mares that are 3-12 years old, of Henneke body condition score 4 or higher, would live in groups of 10-12 mares per pen. Those mares would be examined and have blood drawn approximately monthly, over an 8-month period. Vaccine success for specific aim 1 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. For all formulations, the vaccine would be administered as a single injection in the gluteal muscle, with a sample size of 12 mares per adjuvant type. Treatment type administration will be blinded, until the end of the 1-year study for specific aim 1. Response outcomes would be measured in terms of antibody response to the GDF9 and BMP15 molecules, as measured by enzyme-linked immunosorbent (ELISA) assays (Engvall and Perlmann 1972). Animal health will be checked twice per day by personnel at the BLM-contracted NNCC facility, and any illness or injury will be addressed by the BLM-contracted attending veterinarian for the NNCC facility.

In specific aims 2-4, the two OGF vaccine formulations that caused the greatest immune response during specific aim 1 would be tested in 36 pregnant mares living with fertile stallions in pens, to assess contraceptive effects. These would be mares that were not involved in specific aim 1 of Study A. Age and Henneke body condition score requirements would be the same as in specific aim 1. Mares would be randomly assigned to one of three groups. 12 mares would serve as untreated controls, receiving only inert saline injections. 12 mares per treatment group would receive one or the other vaccine formulation. Mares would live in groups with representatives from each treatment, and with 12 mares and one fertile stallion per pen. Mares would be examined monthly via ultrasound, to check for pregnancy, and have blood drawn for assays of antibody titer, progesterone, and anti-Mullerian hormone (AMH) levels. Assessing effects of OGF vaccine on foal health is another goal. The health of foals born to treated mares would be assessed by observation, ability to stand and nurse, any sign of conformational issues. Foal antibody levels to OGF proteins would also be assessed based on blood samples. Animal health will be checked twice per day by personnel at the BLM-contracted NNCC facility, and any illness or injury will be addressed by the BLM-contracted attending veterinarian for the NNCC facility. Study A and study B are not specifically designed to assess behavioral effects of vaccination in free-roaming wild horses, as the study will take place in a captive setting where observed social dynamics would not necessarily lead to valid inferences about behavioral effects of vaccine treatment in the wild. Some inferences as to behavioral outcomes could be made, though, based on vaccine effects on mares' and foals' hormones.

The NNCC has been selected as suitable for study A and for study B because the pen and handling chute designs are ideal for fertility control studies. The pens were constructed with sturdy materials and high walls, specifically made to be appropriate for housing mares with fertile stallions. These same 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, and in the study described in DOI-BLM-NV-0000-2020-0001-EA. There is a padded hydraulic squeeze chute with split rear doors to allow for animal and veterinarian practitioner safety in pregnancy and related examinations.

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 in specific aim 2-4 (whether vaccinated or untreated controls) 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. It is expected that the non-vaccinated (control) adult mares in specific aims 2-4 will become pregnant at high rates. 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 12) 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.

Other stipulations common to studies A and B include the following. 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 these studies no female humans of childbearing age or younger will be involved with the handling or injection of vaccine. Prior to use in any animals, the vaccines must have any required permissions or registrations from the EPA. During activities, the Lead Contracting Officers Representative (COR) for the BLM contract with the contracted facility would be present, or would delegate supervision duties to another BLM employee. The BLM contract Veterinarian associated with the facility, Animal and Plant Health Inspection Service (APHIS) Veterinarian or other licensed Veterinarian would be on call or on site. Pregnancies will be allowed to go to parturition, and any foals born in the study will be considered wild horses (43 CFR 4700.0-5(l)) and receive proper veterinary care.

2.2.2.B. **SpayVac vaccine study (Study B)**
The proposal for research study B is titled "Improvements to SpayVac Vaccine Efficacy and Duration." The body of the proposal is included in Appendix E.

SpayVac is the trade name for a preparation of PZP vaccine, in which the PZP molecules are encapsulated within liposomes, which are thought to prolong the duration of immunogenic response (Bechert et al. 2013). Like other formulations of PZP vaccine, immune response to SpayVac vaccination can cause antibodies that inhibit fertilization by binding the zona pellucida of a horse's oocytes (EPA 2012), and potentially affecting ovarian function (Bechert et al. 2013, Joonè et al. 2017, Nolan et al. 2018). In several trials in domestic and wild horses, SpayVac has had varied levels of effectiveness and duration. Published results from three trials (Killian et al. 2008, Bechert et al. 2013, Roelle et al. 2017) are reviewed in the proposal in Appendix E. In those trials, some SpayVac formulations led to treated mares having contraceptive effects of 3 years or longer. However, in a fourth trial, the most recently BLM-funded SpayVac trial, fewer than 50% of mares treated with SpayVac in aqueous emulsions had satisfactory contraceptive results beyond 12 months (J. Roelle, US Geological Survey, 2015 unpublished report to BLM from agreement 4500065781). In that study, 30 mares were treated in 2014 with an aqueous formulation of SpayVac and Freund's modified adjuvant, 30 were treated with SpayVac and Freund's complete adjuvant, and 30 control mares received saline or adjuvant only. Within a year, 53%, 70%, and

83% of the same groups were pregnant. Because such high percentages of treated mares had become pregnant, the study was stopped in 2015.

The specific aims of research study B are to assess immunological response and contraceptive efficacy of the most recent SpayVac formulation, which is now produced under different conditions than the 2014 formulation which led to low contraceptive efficacy. The formulation of SpayVac proposed for study B would include addition of modified Freund's adjuvant. Immunological response would be measured in terms of antibody titer levels (Wagner and Freer 2009), and contraceptive efficacy would be determined by having treated mares living with fertile stallions. Mares in study B would receive a SpayVac injection in the neck muscles, in the gluteal muscles, or no SpayVac injection. Specific aim 1 would compare the immunological responses as measured by antibody titers, and specific aim 2 would compare the realized contraceptive effects as measured by pregnancy rates. Both specific aims also include an experimental design structured to test for differential effects, depending on whether the vaccine is administered in neck muscles, or in gluteal muscles.

The SpayVac formulation will be a 1 mL aqueous emulsion (water and oil) that includes 400 µg of PZP antigen enclosed in liposomes, prepared with Freund's modified adjuvant. 55 non-pregnant mares between the ages of 5-15 would be randomly assigned to one of three treatment groups: SpayVac vaccination in the neck muscles (n=20), SpayVac vaccination in the gluteal muscles (n=20), or control group injected with adjuvant and liposomes but no PZP antigen (n=15 total, of which 7 would be injected in the neck, and 8 injected in the gluteal muscles). Mares would not be pregnant at the beginning of the study. The study would most likely begin with treatment of the mares in the winter of 2023.

Holding pens would be comparable to, or identical to those described for study A. As with study A, study B is not designed to be a behavioral effects study. Mares would live in groups of 9-11 mares per pen, of mixed treatment type, at the NNCC. Mares would have blood samples drawn immediately before vaccination, and also in seven months per year during the breeding season, for use in immunological assays of antibody titer and hormone levels. Starting in the spring of 2023, one fertile stallion would be introduced to each pen with mares. Annual pregnancy rates would be quantified for the three treatment groups, based on results from 2023 through 2026. As with study A, additional control group mares may need to be added to the study, to maintain the sample size of open mares in the control group. Other stipulations of study B are noted above, at the end of section 2.2.2.A.

2.2.2.C. **iUPOD IUD study (Study C)**
The proposal for research study C is titled "Performance of the iUPOD Intrauterine Device for Long-Term Fertility Control in Free-roaming Mares." The body of the proposal is included in Appendix F.

Study C would take place largely in the Calico Complex, an area of public lands that is composed of the Black Rock Range HMA, Calico Mountains HMA, Granite Range HMA, McGee Mountain HMA, and Warm Springs Canyon HMA. The Calico Complex is located northwest of Gerlach, Nevada, and southeast of Denio, Nevada, within Humboldt and Washoe Counties. As outlined in Appendix F, the study would involve wild mares being gathered, treated with an IUD or GonaCon vaccine and fitted with a GPS collar, and returned to the Calico Complex for observation. The required gather, and the general use of IUDs on wild horses in the Calico Complex, has been analyzed in a 2019 EA and authorized in a July 28, 2021, Decision Record related to the Calico Complex Wild Horse and Burro Gather Plan (DOI-BLM-NV-W030-2019-EA). That EA and Decision Record, including its analysis of the effects of gathering the wild mares to be included in study C, is incorporated by reference into this EA.

The IUD to be tested in study C is known as the iUPOD device (Gradil et al 2019). It is composed of three subunits, each of which is a magnetic, ovoid shape, coated in inert, medical grade plastic. The magnetic forces cause the three subunits to self-assemble into a rounded triangular shape. However,

because the three subunits can slide past one another, the precise shape of the overall device will vary depending on its position in the uterus. This IUD design has been shown to be safe and effective in domestic horses (Gradil et al. 2019, Hoopes et al. 2021, Joonè et al. 2021).

The primary goals of study C are to quantify the foaling rates for mares treated with iUPOD IUDs, and test for uterine health effects and behavioral effects of IUD use. The BLM would conduct a gather to reduce the herd to a level closer to AML, and to allow for fertility control treatments. Mares considered for the study would be screened for pregnancy by a veterinarian, using transrectal ultrasonography. The iUPOD devices would be placed by a veterinarian in up to approximately 32 mares, ages 5-16 years old, that would be returned to the Calico Complex along with approximately 12 open mares that are not fitted with any IUD, but are treated with GonaCon-Equine fertility control vaccine; the GonaCon-treated mares will serve as a set of 'control' animals for the study. The presence of a foal would be used as the unambiguous indicator of IUD retention in the preceding breeding season (Appendix F, lines 259-261). Behavioral observations will allow researchers to document the frequency of mares' reproductive behaviors. When combined with definitive information about IUD retention based on foaling observations, a retrospective analysis may indicate whether behavior does or does not provide a reliable early indication of IUD retention for time periods before a new foal could be expected with fertile mares. The proposal for study C requested use of mares that are not treated with any form of fertility control, but that is not permissible under the decision record for wild horses in the Calico Complex. Under that decision (DOI-BLM-NV-W030-2019-0019-EA), all mares returned to the range are to be treated with some form of fertility control. Therefore, comparisons of foaling rates will be between iUPOD IUD-treated and GonaCon-treated mares. Generally, vaccination with the GonaCon vaccine is expected to reduce circulating levels of gonadotropin releasing hormone with associated cessation of estrus (Appendix C). The specific effects of GonaCon vaccine use in the Calico Complex were analyzed in DOI-BLM-NV-W030-2019-0019-EA, which is incorporated here by reference. GonaCon-Equine vaccine treated mares will not be restrained or treated with any sham IUD handling activities. Notwithstanding the proposal (Appendix F), it is a reasonable to compare contraceptive effects of the iUPOD IUD and GonaCon vaccine, because in most HMAs the BLM is likely to only return mares to the range who have been treated with some form of fertility control. Uterine biopsies would be collected from mares that receive IUDs or are treated with GonaCon, to facilitate before and after comparisons. Researchers will also be able to quantify foaling rates and behaviors for individually identifiable, ungathered, untreated mares who associate with GPS-collared mares, though it may not always be possible to locate those unmarked animals at will.

Consistent with DOI-BLM-NV-W030-2019-0019-EA, all the mares in the study would be body condition 3 or better, with preference for body condition 4 or better. BLM would either contract for animal gather and transport services in the Calico Complex, where on-range aspects of study C would take place, or may conduct animal gathers and handling there on an in-house (BLM-led) basis. BLM either manages animal care and maintenance at BLM off-range corrals, or contracts for the care and maintenance of excess wild horses removed from the range at other facilities. After gather and transport, mares participating in study C would be screened for pregnancy at a facility that has adequate animal handling facilities, such as the PVC or the NNCC; mares in the study that receive iUPOD IUDs or GonaCon vaccine would be treated at the same facility. The proposal for study C requests treating and studying effects of the IUDs in yearlings, but no yearlings would be included in study C even though the proposal requested to do so, because the analysis in DOI- DOI-BLM-NV-W030-2019-0019-EA was for IUD use in mares aged 5 or older only. Foaling outcomes would be recorded for IUD-treated and GonaCon-treated mares during four years after mares are returned to the range. A set of behavioral measures would be recorded for treated and untreated mares in the first two years after mares are returned to the range. After 4 years, the BLM would attempt to recapture iUPOD-treated and Gona-Con treated 'control' mares from the HMA. Uterine health effects of the IUDs would be assessed, on the basis of biopsies taken at the start of the study, and 4 years later for those animals that are recaptured. Treated mares may or may not be re-

released to the range after that gather, consistent with DOI-BLM-NV-W030-2019-0019-EA and depending on the status of the herd size at that time.

All mares that are returned to the range would be marked with a uniquely-numbered RFID chip in the nuchal ligament of the neck, and individually marked with a numbered freeze mark on one or both hips, to allow for individual identification from a distance. A subset of mares included in the study would be fitted with GPS radio-telemetry collars. These would periodically record the mares' locations, and would allow for researchers to find the animals by homing in on the very high frequency (VHF) radio beacon. Each mare that is treated with the IUD would be GPS radio collared, as would approximately 12 of the open, GonaCon-treated mares. Mares receiving GPS radio collars will be restrained in a hydraulic squeeze chute. Such GPS collars were analyzed in DOI-BLM-NV-W030-2019-0019-EA and have been proven safe and effective in wild horse mares (Collins et al. 2014, Hennig et al. 2019, Schoenecker et al. 2020, Schoenecker et al. 2022). Safety protocols would include the requirement that all collars would have two independent mechanical drop-off mechanisms: one that is timed to release on a pre-planned date, and one that can be triggered remotely by ultra high frequency (UHF) radio signal. King et al. (2022) review the use of braid-in GPS tail tags in wild horses. While such tags can be useful in both mares and stallions, they are not suitable for any study that lasts more than about 6 months, because the mean time length that such tags stay on horses was 8 ½ months. Researchers would locate and observe each collared animal monthly to conduct welfare checks, document any presence of a foal, and record behaviors of collared horses and the other horses in their social groups. In the event that a treated mare is determined to need of veterinary care to address an IUD-related health outcome, the radio collar VHF beacon could allow for the BLM to locate the animal and provide that care after capturing the mare by means of bait/ water trapping or a very small-scale, targeted helicopter gather.

2.2.3 Alternative 2: No Action

Under the No Action Alternative (Alternative 2), the safety, efficacy, or duration of effect of any of the fertility control methods contemplated in the Proposed Action would not be tested. The No Action Alternative would not meet the Purpose and Need identified in section 1.3. Available information about effects of these fertility control methods would be limited to studies outside of the BLM's direct involvement. In future WHB management actions, the BLM could decide to use of any of those fertility control methods, subject to NEPA analysis of information available at that time, but would not have the benefit of information that would have resulted from the studies in the Proposed Action.

2.3 Alternatives Considered but Eliminated from Detailed Analysis

Sometimes alternatives are suggested or proposed that on examination do not adequately respond to the purpose and need for the action, are technically or economically cost prohibitive, are not ripe for consideration, are remote or speculative, are substantially similar in design to an existing alternative, would have substantially similar effects as an existing alternative, or the authority does not exist to approve such actions (BLM NEPA Handbook, Section 6.6.3). In such cases, these alternatives are usually eliminated from detailed analysis. Alternatives that were considered and eliminated from detailed analysis are described below, along with the rationale for their elimination.

2.3.1 ZonaStat-H or PZP-22 PZP Vaccine Study

An alternative in which either of the currently-used PZP vaccines (ZonaStat-H or PZP-22 pellet vaccines) would be tested in a pen trial was not considered here for detailed analysis. An additional trial of existing PZP vaccines would not provide BLM with information about a new method of potentially long-lasting mare fertility control. This alternative was not analyzed because it would not respond to the purpose and need. Both of those formulations of PZP vaccine have already been shown to not cause long-lasting contraceptive effects from one dose. 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-22 vaccine pellets were tested in pen trials at the NNCC from 2011 to 2014, in the same pens that would be used in part of the Proposed Action, and using similar methods for rotation of fertile stallions with bands of treated and non-treated mares. In the most recent trials for the nominally long-lasting PZP-22 vaccine pellet formulations (at NNCC), extended infertility was not observed, and the trial was discontinued after higher than expected pregnancy rates were observed in treated mares after a short time period (J. Turner, University of Toledo, unpublished report to the BLM from agreement L10AC20431). The physiological and contraceptive effects of PZP vaccines are fairly well understood, and another pen trial with wild horses is not needed for BLM to continue using this vaccine in wild horse management.

2.3.1 GonaCon Vaccine Study

An alternative in which the GonaCon vaccine would be tested in a pen trial was not considered for detailed analysis. An additional GonaCon vaccine trial would not respond to the purpose and need, as it would not provide BLM with information about a new method of potentially long-lasting mare fertility control. GonaCon is already approved for use as a fertility control vaccine in wild horses and burros (EPA 2013), and field trials have already demonstrated that GonaCon is an effective vaccine, typically causing long-lasting efficacy after a second hand-injected dose is administered (Baker et al. 2018). 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 using this vaccine in wild horse management.

2.3.3 Conduct the Studies in Domestic Mares

An alternative where the proposed studies would take place with domestic horses outside of BLM custody would not respond to the purpose and need and, therefore, was dismissed from detailed study. Most importantly, wild horses are the intended population of use for the OGF vaccine, SpayVac vaccine, or IUD methods contemplated in the Proposed Action. It is worthwhile to test whether these vaccines or IUDs work safely and effectively in wild horses. While there should be no innate or genetic physiological differences between domestic and feral horses (including BLM-managed wild horses), it is possible that some unidentified phenotypic or physiological traits that are idiosyncratic to wild horses could influence fertility control method effectiveness, as noted in the 2005 WHB Strategic Research Plan (BLM 2005). For example, unlike domestic horses, most wild horses have not typically been exposed to extensive human handling or to numerous vaccines over the course of their lives. There is some possibility that the oocyte growth factor vaccine or SpayVac 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, because over their lives domestic horses may be exposed to a wide range of vaccinations, unlike wild horses. Likewise, the safe and successful placement of IUDs in wild horses may present different veterinary procedural challenges than would the same IUD placement in domestic horses. Having lived apart from humans, wild horses can be expected to be more potentially fractious during handling, and this could influence the long-term success of the method, with respect to mare fertility control. Because a purpose of the studies is to potentially inform future wild horse management decisions about the applicability and long-term effects of these methods in wild horses specifically, aspects of wild horse immunology or animal handling that could influence contraceptive outcome would not be so easily identified if the studies were to take place in domestic horses.

2.3.4 Conduct Studies at a Different Facility

An alternative that involves conducting studies A and B and the off-range handling portions of study C at a different facility than the NNCC would be substantially similar in study design and have substantially similar effects to the Proposed Action. Because of how studies A and B and the off-range components of study C are designed, any change in off-range location would not be expected to change the nature of the expected effects. In other words, so long as the studies are performed in holding pens that were

specifically designed for animal safety in fertility control pen trials, the location of the studies should not impact the potential effects. An alternative that involved conducting the studies at a different facility was therefore eliminated from detailed analysis in accordance with the BLM NEPA Handbook (BLM 2008).

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). Effects means changes to the human environment from the Proposed Action or alternatives that are reasonably foreseeable and have a reasonably close causal relationship to the Proposed Action or alternatives, including those effects that occur at the same time and place as the Proposed Action or alternatives and may include effects that are later in time or farther removed in distance from the Proposed Action or alternatives (40 CFR 1508.1(g)). Effects include ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects. Effects may also include those resulting from actions that may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial (40 CFR 1508.1(g)(1)).

3.1 General Description of the Affected Environment

3.1.A and 3.1.B

Studies A and B would take place at the NNCC. 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. Annual 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 has been the location for previous wild horse fertility control vaccine trials including, most recently, trials of an earlier formulation of OGF vaccine, as described in the NEPA analysis in DOI-BLM-NV-0000-2020-0001-EA. The NNCC grounds include equine facilities suitable for wild horse care, maintenance, and handling. The facilities include a number of large pens that were custom-built to accommodate fertility control pen trials, 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 animal handling, blood sampling, vaccination, pregnancy screening inspections, IUD placement, 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 studies would take place. As a prison, the NNCC has public security and safety considerations that preclude public access to the study area. The pen study area is not in an area open to or safe for the public, in contrast to the area at the NNCC used for scheduled adoption events where members of the public can be safely accommodated. No photography, recording or videography is allowed in the wild horse maintenance and handling areas of the NNCC. When BLM staff work in the animal maintenance and handling areas of the NNCC, the NNCC does not allow BLM staff to bring cameras or cell phones. Although the public can come onto some portions of the NNCC grounds for scheduled wild horse and burro adoption events, those events are held in an area where public safety can be ensured. The area where the wild horse and burro adoption events take place is separate and distinct from the area where the inmates care for and train excess wild horses removed from the range, as well as from the area where the horses in the separate studies would be housed, cared for, vaccinated, checked for pregnancy, and handled for IUD insertion.

3.1.C
The analysis in this EA is based on the BLM's current intention that the iUPOD IUD study would take place within the Calico complex of HMAs, which is composed of the Black Rock Range HMA, Calico Mountains HMA, Granite Range HMA, McGee Mountain HMA, and Warm Springs Canyon HMA. Those HMAs are located in northwest Nevada. Herd management activities there are led by BLM Nevada State Office; Winnemucca District Office; Black Rock Field Office. Conditions at the Calico complex are described in DOI-BLM-NV-W030-2019-0019-EA, which is incorporated by reference. Animals captured at the complex will be transported to a corral facility with appropriate facilities (such as the PVC or the NNCC), for pregnancy screening and IUD placement, by a veterinarian, and GPS radio collar fitting. After treatment and observation, horses would be returned to the HMAs in a free-roaming condition.

This complex of HMAs and the management considerations that led to a Decision Record in July 2021, to conduct gathers, removals, and use fertility control vaccines and IUDs in wild horse management are described in DOI-BLM-NV-W030-2019-0019-EA. All IUD-treated mares would be collared. The approximately 32 GPS-collared mares considered for treatment with a flexible IUD prior to release back onto the public range and the approximately 12 open, GPS-collared, GonaCon-treated mares that would also be returned to the range would come from a larger pool of gathered Calico complex mares that would have first been screened by a veterinarian at a corral facility where there is a suitably designed, padded hydraulic squeeze chute for the required veterinary ultrasound examination, to determine pregnancy status, such as the PVC or the NNCC. The padded squeeze chute design required for veterinary ultrasound-based pregnancy screening is the same as for the placement of an IUD, which requires a rear door that is split to allow access to the hind end, while protecting the veterinarian from any potential kick.

3.2 Description of Affected Resources/Issues

Within the overall Proposed Action, studies A and B would take place on the grounds of the NNCC, in an area that does not include any federal lands. Except for the actions associated with animal transport, pregnancy screening, IUD placement, and GPS collar fitting, study C would take place at the Calico complex of HMAs, where impacts of wild horse gathers and fertility control have already been analyzed under DOI-BLM-NV-W030-2019-0019-EA, which is incorporated here by reference.

The table in Appendix G lists elements of the human environment subject to requirements in statute, regulation, or executive order which must be considered. In addition to the critical elements listed in Appendix G, the only resources that may be affected by the Proposed Action are wild horses that would be included in the Proposed Action. The potential impacts to resources that are associated with the gather and removal of excess wild horses and burros, or (in the case of study C) the use of IUDs and GonaCon vaccine as a fertility control method and placement of GPS collars, have already been analyzed in previous NEPA documents (See Appendix G), which are incorporated here by reference. The affected environment, relative to wild horse resources, is described below.

3.2.1 Wild Horses

The ecological context of resource scarcity and the fragility of arid western rangelands is a motivation for development of effective long-term fertility control methods for wild horses. Wild horses are important components of the public lands designated for their management. The majority of HMAs have wild horse herd sizes that are far larger than appropriate management levels. When wild horses are overpopulated relative to available forage, water, and other natural resources, there can be negative consequences on wild horses and their habitats. Drought exacerbated by climate change can further reduce ecosystem productivity, making it all the more important that herds of wild horses not grow to the point where they degrade available natural resources.

Any wild horses included in studies A or B of the Proposed Action would have been previously gathered and removed from the public range as excess animals under previous BLM decisions that followed NEPA

analysis, public comment, and issuance of decision records. The length of time since the excess horses were removed from the range may vary by individual animal. Their ages would be between 3-15 years old at the time of the start of the Proposed Action, and their Henneke body condition scores would be at least 3, with a preference for animals with scores of 4 or more. Any stallion that would be included in any of the studies contemplated would still be intact (potentially 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 from other information that may be available or diagnosable about the mare's current pregnancy status.

Regardless of whether the authorized officer authorizes the Proposed Action or any part of it, the BLM will continue to manage the wild horses of the Calico complex in accordance with the 2021 decision record (DOI-BLM-NV-W030-2019-0019-EA), which provides for removal of excess animals, application of fertility controls (including IUDs and fertility control vaccines), and fitting some animals with GPS telemetry collars.

All animals at gathers, in handling and transportation, and at BLM-managed or BLM-contracted WHB care facilities, whether included in the proposed study or not, are properly fed, watered, transported, and provided veterinary care, consistent with BLM comprehensive animal welfare standards for their maintenance and care (Appendix B).

4.0 Environmental Consequences

4.1 Introduction

This section of the EA documents and considers the potential environmental effects which would be expected with implementation of the Proposed Action or the No Action Alternative. The data and level of analysis are commensurate with the importance of the possible impacts. The effects are generally described qualitatively, though some quantitative discussions may also be included.

4.2 Wild Horses

Impacts of Proposed Action Alternative

All the wild horses that would be included in studies A and B would have been previously gathered and removed from the range and already be living in captivity at the NNCC. The impacts of gathering and removing those animals were considered in previous NEPA analyses and are not included here. The impacts analysis that follows for studies A and B 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 to the horses being gathered, transported, and handled, and removed, or actions that resulted directly from their prior gathering.

By comparison, the wild horses that would be included in study C would still need to be gathered. The impacts associated with that gather, and the impacts generally associated with IUD and vaccine application, were analyzed in DOI-BLM-NV-W030-2019-0019-EA, which is incorporated here. As a result, the impacts analysis that follows for study C is mostly limited to potential impacts that could result from the Proposed Action, though there are some descriptions of previously-analyzed impacts included, for the purpose of providing context or describing the overall actions of study C.

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 2021c). The CAWP (Appendix B) 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 for all animals may include insertion of an RFID chip in the nuchal ligament and freeze-marking, for the purpose of easily identifying individual animals. After capture from the Calico complex, mares in study C could be transported to a corral with appropriate facilities, such as the PVC or the NNCC, for pregnancy screening by a veterinarian. Pregnancy screening takes place in a hydraulic chute with independently operable upper and lower rear doors, so that the mare can be safely restrained and the veterinarian has access to the mare's hind end. After clearing the mare's rectum of fecal material with a gloved hand, the veterinarian may initially use transrectal uterine palpation to feel for presence of a large fetus. If no fetus is palpable, the veterinarian would use a small ultrasound probe to conduct transrectal screening for the presence of a small fetus. Mares in study C that are not pregnant could have a uterine biopsy sample taken (as described in Appendix F), be treated with an iUPOD IUD (as described in Appendix F) or GonaCon vaccine, observed during temporary holding, fitted with a GPS radio collar, and then be transported back to the range.

The BLM has supported other ecological studies in which wild mares and jennies were radio collared with similar collars and were monitored for health and any effects of collars via monthly welfare checks. Such collars, with the timed and remotely triggerable drop-off mechanisms, have been used in Adobe Town, Conger, Eagle, Frisco, Swasey, and Sulphur HMAs (mares) and in Sinbad HMA and Lake Pleasant HMA (jennies). For researchers to fit a radio collar to a mare requires that the animal is briefly restrained, and this can entail some transient stress to the animal, along with the low probability for injuries that would be associated with animal handling in a squeeze chute. After fitting, there is the low-probability potential for a radio collar to cause skin or tissue abrasion, especially if it is not properly fit, although this is unlikely. If a radio collar is poorly fit, it may slide over a horse's ear or ears, which could impede neck mobility to a limited degree. Improper radio collar fit is most common in stallions, which have a different neck musculature allometry than mares, but no stallions would be collared in the Proposed Action. If the researchers observe tissue abrasion or a collar remaining over the animal's ears during the monthly visual welfare checks of radio-collared mares, the researchers will send a radio signal to cause the remotely triggered drop-off device to open the collar, and it will fall off the mare. So long as the collar does not cause injury, there is no expectation that it would impede eating, drinking, mobility, social interactions, or other behaviors. USGS researchers have not reported radio-collared animals becoming stuck on vegetation or other objects in the environment. Collars weigh less than 1 kg, which is a load that is not expected to cause any undue hardship in such a large animal as a mature horse. In a study on the effects of comparable model radio collars, there was no measurable difference in horse behavior or body condition, based on comparisons of collared / tagged versus control animals (Schoenecker et al. 2020). The timed and remote-release drop off mechanisms have proven safe for use; the same authors who urged researchers to report any problems with equid radio collars in Hennig et al. (2020) have not reported such problems in their subsequent papers (Hennig et al. 2018, Esmaileh et al. 2021, Hennig et al. 2021, King et al. 2022, Hennig et al. 2022). If researchers observe any health problems in radio-collared horses that cannot be resolved by causing a remotely triggered collar drop-off but which require veterinary attention, those animals could be targeted for capture by small-scale helicopter capture or bait-water capture, for the purposes of health treatment, if that is deemed necessary by the BLM and a veterinarian.

It is possible that there could be conflict between individual animals that live together in pens. Such impacts are known to occur intermittently in off-range facilities. An example of an indirect individual impact could be a brief 1 second to 2 minute skirmish between animals; usually such conflicts are between studs, and would not be expected in bands with only one stud and a number of 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 off range corral facilities, including at NNCC. The same pens at NNCC that would be used for proposed studies A and B were previously used in a 2011-2013 pen trial of pelleted versions of a PZP vaccine, and of a different OGF vaccine formulation. In the PZP 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 PZP trial being about twice as high as proposed for studies A or B, no injuries to mares, foals, or stallions were mentioned in progress reports or the final report from that work (J. Turner, University of Toledo, unpublished reports to BLM).

Mares in the Proposed Action that are not treated with any fertility control method but live with fertile stallions would likely become pregnant and produce foals over the course of the studies. For studies A and B, this could result in foals that will be born in captivity. Foals born to wild mares in a BLM-managed facility, or in the wild, would be deemed wild horses (43 CFR 4700.0-5(l)), and would stay with their mother through the age of weaning (typically 6 months or older). For foals born in captivity, BLM would seek to place these foals into private care through adoption after weaning. Researchers in study A may examine or draw blood from foals born to vaccine-treated mares, to monitor their reproductive development. It is not expected that any treated or untreated mare in any of the studies would reject a foal. If a mare dies or must be humanely euthanized during the study, every effort would be made to provide appropriate care to any 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. For foals born on the range in study C, it is expected that those foals would live with, and in the manner of, other wild horses in that HMA.

In the event of any injury or health concerns, any decisions to humanely euthanize animals would be made in conformance with BLM policy (BLM IM 2021-007).

Fertility Control Studies' 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). Potential direct, indirect, behavioral, and genetic effects of potential fertility control methods are explored in greater depth in Appendix C, but are summarized here. Most mares are expected to recover quickly from the stress of handling, and none is expected to suffer serious long term effects from any of the treatments, other than the direct consequence of temporary or permanent infertility, which is the desired outcome of the fertility control methods being tested. Randomization of treatment type for mares in all three of the proposed studies should minimize the effects of individual covariates on estimated treatment effects. In all three studies, treated mares may become only temporarily infertile, or may remain infertile for many years. None of the studies would last over 5 years. Some inferences about long-term effects of the methods being tested may be reasonably made at the conclusion of the studies. However, it may not be possible to definitively determine whether any of these treatments would cause permanent sterility, because mares can live well over 20 years. If the methods in studies A, B, or C did cause permanent infertility in some or all of treated mares, that would be consistent with the desired contraceptive effect, and would be similar in outcome to mares treated multiple times with existing PZP vaccines where some horses can become effectively sterile from repeated PZP doses (Nuñez et al. 2017).

In studies A and B, the vaccine preparations are not expected to cause long-lasting harm to any treated mare, though they are expected to cause at least temporary infertility. In this sense, the vaccines are comparable to other immunocontraceptive vaccines that BLM uses in wild horse management, such as PZP vaccines and GonaCon vaccine. Treated mares in studies A and B would receive a single dose of the oocyte growth factor vaccine or the SpayVac vaccine, by hand. The intended purpose of these vaccines is to cause long-term infertility. Treated mares could experience immune responses to any of the vaccine components.

In study A, the oocyte growth factor vaccines 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 D). Elevated levels of antibodies that are specific against BMP15 and GDF9 should follow vaccination with oocyte growth factor vaccines, which in turn attenuates and disrupts oocyte and / or follicular development (Appendix D). 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 D). Another specific result of OGF vaccination may be a lack of observed estrous cycling (Appendix D). 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 BMP15 and GDF9 indicated that there was a prolonged lack of estrus in mares, even after the level of BMP15- and GDF9-specific antibodies decreased (Appendix D). Of 10 mares treated with the multi-injection oocyte growth factor vaccine against GDF9 and BMP15 (Appendix D), all 10 were infertile in the first year after vaccination, and 9 of 10 were infertile in the second year (NWRC, unpublished data). The reproductive effects of the OGF vaccine formulations being tested, whether temporary or long-lasting, are expected to be comparable to what is observable in mares' seasonal anestrous period, in the sense 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 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 OGF vaccination may lead to a lifelong dysregulation of oocytes or their growth factors from the ovaries; this could be interpreted as a form of vaccine-induced sterility.

In studies A and B, systemic and 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). There may be transiently elevated body temperature, injection site soreness and short-term injection site swelling, consistent with short-term immune response to foreign molecules in the body. Vaccines formulated with the Montanide Pet Gel A adjuvant may cause body temperature to rise for up to a few days by up to about 1 degree C and localized (i.e., less than 20 cm^2) injection site reactions with transient swelling lasting less than 1 week (Deville et al. 2011, Davis et al. 2018, Nolan et al. 2019), but with no observable change in behavior (Deville et al. 2011). SpayVac vaccine preparations are known to cause injection site reactions (Roelle et al. 2017), in a manner that is comparable to other PZP vaccine formulations that use Freunds modified adjuvant or Freunds complete adjuvant. Such site reactions may include transient swelling, persistent subcutaneous swelling, and purulent abscesses (e.g., Roelle and Ransom 2009). Similarly, the Adjuvac adjuvant considered for some formulations in study A, or the conjugation of antigens to mollusc hemocyanin, is known to have the potential to cause injection site reactions that 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). The adjuvants in the other formulations in study A are not anticipated to differ noticeably from similarly mild reactions, which may include transiently elevated

body temperatures, localized and temporary injection site reactions, and enhanced activation of the body's immune response that is characteristic of short-term immune responses to foreign molecules in the body. Adjuvants 'A' and 'B' both are approved for veterinary use by the USDA (Appendix D). The BLM has been informed that preliminary results submitted to that agency as part of the approval process demonstrated that experimental control animals which were treated only with adjuvant (i.e., without inclusion of any antigen in the dosage) did not exhibit any adverse effects. It can be expected that any site reactions for vaccine treatments that include adjuvants 'A' or 'B' would depend largely on the antigen. However, even though some antigens alone may cause adverse effects in some treated animals, the OGF proteins that would be used as antigens in study A are native to horses, are not highly immunogenic, and caused no injection site reactions even when conjugated to a mollusc hemocyanin carrier protein (Davis et al. 2018). Separately, even if there are site reactions, it is not expected that SpayVac injection in the neck will limit the range of motion in the neck for treated animals in study B. As noted in Appendix E, the neck musculature is a commonly used area for domestic horse intramuscular injections.

It is not expected that vaccines in study A or B would cause miscarriage in pregnant mares, because the vaccine antigen and adjuvant components are not expected to disrupt 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 activities 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, because the mares included in studies A or B would not have been gathered immediately prior to the study, 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 in study A would have compromised ovarian function, but this is unlikely because mare 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.

Neither infanticide nor foal stealing are expected to increase over naturally occurring, very low, levels for animals treated in studies A, B, or C. 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 application in wild horses or burros. A different phenomenon, "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 treatments 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 relatively 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."

In study C,[3] all potentially IUD-treated and GonaCon-treated mares would be screened for pregnancy, and shown to be not pregnant at the time of treatment. The same methods may be used to identify non-pregnant mares as were described for studies A and B. Initial veterinary screening for pregnancy may be via transrectal palpation of the uterus; this method can reliably identify mares that have somewhat

[3] As noted above, the wild mares that would be included in study C would be gathered pursuant to the July 28, 2021, Calico Complex Gather Plan. The environmental effects of that gather plan were analyzed in the Calico Complex Wild Horse and Burro Gather Plan EA. That EA, which is incorporated by reference into this EA, analyzes the environmental effects of the gather that will precede implementation of study C.

advanced pregnancy. A more determinative screening that can identify very early pregnancies is veterinary transrectal ultrasound. Both methods require physical restraint in a padded hydraulic squeeze chute and clearing of feces from the rectum. The choice to administer a mild sedative would be at the discretion of the attending veterinarian. In some circumstances, the attending veterinarian may choose to use hormonal screening to identify mare pregnancy status.

As described in Appendix F, placement of a flexible iUPOD IUD in study C would both require restraint in a padded hydraulic squeeze chute, and handling by a veterinarian. This approach requires clearing of feces from the rectum, and cleaning of the perineal area. The manufacturer's technical information sheet for the iUPOD IUD (Pearl Pod 2022) identifies possible contraindications for iUPOD use, which mostly relate to a veterinary history of poor reproductive organ system health. While the mares are in the padded hydraulic squeeze chute, researchers will prescreen mares with the pregnancy check and an examination of the ovaries, but because the mares are wild, there will be no prior veterinary records about the mares' reproductive health histories. However, given the high annual growth rates in the Calico herd and associated high fertility rates there, it is reasonable to expect that the wild mares potentially included in the study will generally be reproductively healthy. Still, because the wild mares do not have a veterinary history, it remains possible (although unlikely) that iUPODs will be placed in mares with contraindications As such, while there could be impacts from placing iUPOD IUDs in mares with contraindications, pre-screening should make that unlikely, and the outcomes from iUPOD IUD placement in wild mares with favorable pre-screening outcomes are not expected to include substantial complications. The radio-collared mares will be located with telemetry monthly, and obvious signs of discomfort should be visually observable.

Mares in study C would be gathered, handled, and cared for in a manner consistent with the decision record for the Calico Complex Gather Plan. The impacts of gathering, handling, transport, and care are detailed in the EA that supported the Calico Complex Gather Plan, which is incorporated here by reference. Mares would need to be transported from the gather location and temporary holding to a prep facility with a suitable padded squeeze chute where a veterinarian can make pregnancy assessments. Non-pregnant mares may be treated with an IUD or GonaCon vaccine. The particular choice of IUD to be used in study C would be the iUPOD device (Gradil et al. 2019, Gradil et al. 2021, Hoopes et al. 2021), which is a flexible IUD, comparable in size to the Y-shaped silicone IUD for use in feral mares (Holyoak et al. 2021, Lyman et al. 2021). IUD-treated and GonaCon-treated mares in study C would be restrained and have a small uterine biopsy taken at the start of the study. Mares that are recaptured at the end of the study would also have small uterine biopsy samples taken. Prior to IUD application in study C, mares in the treatment group would be lightly sedated (see section C4 of Appendix F). Lubrication would include a local drug that has the effect of reducing muscular contractions. The veterinarian would gently pass three separate IUD subunits through the cervix by hand. The subunits assemble by magnetic force within the uterus. Both IUD-treated and GonaCon-treated mares would also receive a dose of progesterone formulated to last approximately 10 days, to reduce uterine contractions and any breeding behaviors in the initial period immediately after IUD-treated mares have IUD placement. At the end of the study any recaptured, treated mares could have the IUD removed by a veterinarian. After restraint, cleaning of the perineal area, and treatment with a muscle relaxant, a thin flexible rod with a magnetic tip is passed through the cervix to attract and remove the IUD. The direct effects of IUD presence are expected to be prevention of pregnancy, and possible chronic, low-level inflammation of the uterus, as discussed in more detail in Appendix C. In recent studies, IUD presence has been shown to possibly change the timing of estrus cycles, but in most treated mares has not caused the cessation of estrus cycles (see Appendix C). A padded squeeze chute or a working chute will be used to hold the 12 mares treated with GonaCon vaccine. Other possible effects of animal handling to treat mares are comparable to the handling effects analyzed in DOI-BLM-NV-W030-2019-0019; injuries and stress are possible during capture, transport, and handling but the BLM follows the CAWP (Appendix B) to minimize the physical and psychological risks to captive wild horses. After treatment with an IUD or GonaCon vaccine, mares could be help in

temporary holding for observations or, in the case of GonaCon-treated mares, until they receive a second dose of the vaccine. Treated mares would need to be transported back to the range for release back to lands of the Calico complex, in areas close to the locations where they were captured.

Fertility Control Studies' Indirect Effects

Potential indirect effects of potential fertility control methods are explored in greater depth in Appendix C, but are also summarized briefly here. One expected medium-to-long-term, indirect effect on wild horses treated with a successful fertility control methods would be an improvement in the mares' overall health. This result has been observed in mares treated with immunocontraceptive vaccine (Turner and Kirkpatrick 2002). Contraceptive mares would not experience the metabolic and energetic demands 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 subsequently returns to fertility, her future foals could 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. Fertility control treatment may similarly 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 suggest that many of the immunocontraceptive vaccine treated mares were larger than, maintained higher body condition than, and had larger healthy foals than untreated mares.

Vaccination with OGF 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. Treatment with flexible IUDs may lead to a prolonged period between estrus cycles. However, lack of estrus behaviors, or prolonged periods between estrus behaviors, is not expected to fundamentally disrupt treated mares' 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 within bands of other horses (Collins and Kasbohm 2017). In terms of reproductive behavioral effects and any attendant effects on social structure in the wild, there is no expectation that IUD-treated mares would cease to affiliate with other wild horses in social bands, or to roam freely, as would be expected for any other wild mares. One might reasonably expect that IUD presence could lead to behavioral effects that may span the range of those observed by PZP vaccine treatments that lead to estrus cycling throughout the breeding season, and GonaCon vaccine treatments that lead to a cessation of estrus cycling (Appendix C).

Mares treated with the immunocontraceptive vaccines may have long-lasting granulomas at the vaccine injection site. 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.

Two studies have raised a 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 that treated herds will exhibit an increased frequency of animals with poor immune system health 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). However, 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, BLM is not aware of any studies 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.

It is possible that wild horse herds on the Calico complex will have marginally lower growth rates than might have been the case if study C does not take place. Treating open mares with GonaCon vaccine is the principal difference between actions under study C and actions under the decision that followed DOI-BLM-NV-W030-2019-0019; under the previous decision, mares receiving GonaCon could be either pregnant or open. As a result, there could be a marginally smaller number of foals born to GonaCon treated mares in the first year after vaccine treatment. The herd on the Calico complex is extremely likely to still grow over time because several mares in the Calico complex are expected to still be untreated with any form of fertility control during the study. If the growth rate is such that wild horses in the Calico complex remain at AML for a slightly longer period, there could be some degree of improvement to rangeland health conditions at a marginally faster rate or for a longer period than might have been the case if study C did not take place. If an IUD-treated mare were to die on the range, the presence of the IUD is not expected to cause negative environmental impacts. The elliptical shape of the device, lacking any sharp edges, would most likely minimize the risk of GI perforation or obstruction in scavengers or carnivores if they were to ingest it. Across landscapes and ecosystems of the scale encompassed by the Calico complex it is hard to imagine that the very low risk of intestinal obstruction to a very limited number of predators or scavengers could have measurable or ecologically substantial effects.

The testing of fertility control methods under the Proposed Action is not expected to limit genetic diversity in free-roaming herds of wild horses. Any future wild horse herd planning decisions by which BLM would treat wild horses with any of the methods contemplated in the Proposed Action would be

subject to consideration and analysis, consistent with NEPA. Use of IUDs in study C as a part of wild horse management in the Calico complex has already been analyzed in DOI-BLM-NV-W030-2019-0019-EA and the choice of IUD type is not expected to cause any differential effects on genetic diversity that would not have already been possible through application of a different type of IUD. More generally, 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 National Academies of Sciences (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 improve local herd traits and maintain high genetic diversity, consistent with the BLM WHB management handbook (2010) and NEPA analyses for specific HMAs. The NAS report (2013) includes extensive data on pairwise genetic 'fixation index' values for sampled WHB herds, which confirm that WHBs in the vast majority of HMAs are genetically similar to animals in multiple other HMAs.

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 a vaccine in study A or B leads to long-term infertility, it may be of interest to determine whether there are any post-partum 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 duration of studies A and B in the Proposed Action.

At the end of the studies, animals in study C may or may not remain on the range consistent with the previous decision in DOI-BLM-NV-W030-2019-0019-EA. Study C includes a gather at the conclusion of the study, for the purposes of removing any GPS radio collars that have not already been removed via remote drop-off signaling, and to sample a uterine biopsy from each IUD-treated or GonaCon vaccine-treated mare. After that gather, any decision about whether or not to return IUD-treated or GonaCon vaccine-treated mares from this study to the range will be made by BLM managers in the Winnemucca District Office / Black Rock Field Office, consistent with the decision record that followed DOI-BLM-NV-W030-2019-0019-EA. Animals from studies A and B, foals born in BLM-administered facilities to pregnant mares in studies A and B, or any animals from study C that are gathered in the future during the course of the study-ending gather or other BLM herd management activities, 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 has already been analyzed in the applicable gather decisions. It is possible that mares treated with fertility control could be perceived as either more or less desirable for adoption or purchase. However, a history of fertility control treatment is not expected to be a sole cause for why a given mare might not be adopted or purchased.

Impacts of Alternative 2 (No Action)

Under the No Action Alternative, no elements of the proposed studies would affect wild horses. The No Action Alternative would not provide the BLM or other interested parties with quantified information about the specific effects realized by experimental application of the three fertility control methods to wild horses. The No Action alternative also would not have the potential to provide BLM or other interested parties with quantified information about longer-lasting fertility controls, which could lead to lower wild horse population growth rates and improvements in rangeland health. However, even if the Proposed Action is not selected for implementation, the wild horses that might have been included in the Proposed Action would continue to be managed in the wild or in captivity, consistent with the agency decisions that pertain to the herds in which they live or from which they came. Stallions that might have

remained fertile to allow for their participation in studies A or B would most likely be gelded as a typical part of wild horse preparation for private care placement or living in off-range pastures.

4.3 Cumulative Effects

Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. The cumulative impacts study area for the purposes of evaluating cumulative impacts is limited to the facilities and HMAs where the studies contemplated here would take place, and specifically for the wild horses that would be included in the Proposed Action.

4.3.1 Past and Present Actions

4.3.1.1 Wild Horses

Management actions that have influenced the wild horses that may be included in the Proposed Action are primarily wild horse gathers, which led to the removal of those horses from the range and their designation as excess animals under previously issued BLM decisions. The Proposed Action Alternative could cause an incremental change in potentially preventing future reproduction for the mares treated in these studies, with the fertility control methods contemplated. 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. Until and unless they go into private care, wild mares in captivity live exclusively around other mares or with gelded (infertile) males. In the context of over 57,000 wild horses living in some form of off-range holding, the potential loss of reproductive capacity for the relatively small number of wild mares treated in the studies of the Proposed Action (beyond those analyzed and authorized under prior decisions) would not represent a substantial change. IUD and GonaCon treatment in open mares that are returned to the range in Study C could cause marginal differences in overall herd growth rates. If the IUDs are highly successful, this could translate to a marginally lower, but expectedly still positive, overall herd growth rate on the Calico complex, with attendant relative benefits to rangeland health, wild horse body condition, and a potentially prolonged time until the herd exceeds AML.

4.4 Reasonably Foreseeable Future Actions

4.4.1 Wild Horses

The Proposed Action combined with reasonably foreseeable future gathers and management actions is unlikely to affect the genetic health of any wild horse herd. The wild mares that would be included in studies A and B will have already been removed from the range and would not be returned to the wild or reproduce in the wild, so long-term infertility in those animals will not impact the genetic health of wild horse herds. Study C, combined with reasonably foreseeable future gathers and management actions, is also unlikely to affect the genetic health of wild horse herds. As noted above, the BLM expressly considered the use of IUDs and fertility control vaccines in the Calico Complex Gather Plan. Those impacts of study C have already been accounted for and will not be additive.

Various forms of fertility control may or may not be used in future wild horse and burro herd management, to help with the goals of maintaining herds at or near AML, reducing fertility rates, reducing the frequency of gathers and removals, and ultimately achieving and maintaining a thriving natural ecological balance on the public lands. Whether any of the methods in the Proposed Action do or do not lead to long-term mare infertility, or to sterility, any future BLM herd management actions considering their use would also require additional NEPA compliance. The results of the Proposed Action could help to inform BLM in future decisions.

Additional studies of the short-term and medium-to-longer-term effects of any of the methods included in the Proposed Action could be warranted in the future, though the need for such research has not yet been identified as meriting BLM support. In such possible future studies, for example, some treated mares that

have been successfully contracepted under the Proposed Action, or their foals, might be monitored to assess how long a fertility control method is successful. For example, if foals born to treated mares in study A have elevated levels of antibodies specific to OGF proteins at birth, this may warrant further monitoring. At this time, there is no specific proposal or plan to conduct such studies.

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. 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 to 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 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 was 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 horses and burros rare in the western United States or in other countries. Over 64,000 adult wild horses and over 17,000 adult wild burros roamed public lands as of March 1, 2021. Those numbers do not include at least 9,500 WHB on US Forest Service lands, and at least 100,000 feral horses on tribal lands in the western United States (Wallace et al. 2017, Beever et al. 2018, Schoenecker et al. 2021).

Because any future herd management actions that include long-lasting mare contraception, including possible 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 any of the fertility control methods in the Proposed Action cause long-lasting contraceptive effects, then it is reasonable to expect that BLM might develop guidelines for use of those methods in the future, similar to standard operating procedures that exist for other fertility control methods. There are suggested guidelines for fertility control use in BLM wild horse herd management (BLM 2010) and it is reasonable to suppose that the agency will update those suggestions at some point in the future.

5.0 Monitoring and Mitigation Measures

BLM contracting officer's representatives assigned to any facility contracts would be responsible for ensuring contract personnel abide by the contract specifications and the CAWP (Appendix B) in the course of any studies using contracted facilities. Animal care will also be in keeping with protocols approved by Institutional Animal Care and Use Committees, from the participating research institutions for each study. Out of an abundance of caution, the fertility control vaccines in studies A and B will be handled with extreme care, and making use of appropriate personal protective equipment, such as is used for application of GonaCon vaccine or ZonaStat-H vaccine. Ongoing monitoring of animal health would continue. BLM would continue to contract with attending veterinarians at any WHB facilities involved with the studies, so that there is veterinary care available as needed. This would include monitoring of injection site reactions for studies A and B. The health and welfare of any radio-collared animals in study C would be monitored at least monthly by visual observation, with the aid of radio telemetry to locate the animals. Response variables that gauge the success of the different fertility control methods, for example in terms of immune response or pregnancy status, are identified in the research proposals in Appendices D, E, F.

6.0 List of Preparers

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

Name	Title	Area of Responsibility
Paul Griffin	Research Coordinator	Project Lead
Ruth Thompson	BLM NV WHB State Lead	Logistics and oversight, Nevada
Garrett Swisher	BLM Black Rock FO WHB Specialist	Logistics and oversight, Nevada
Scott Fluer	BLM HQ-261 On-Range Branch Chief	Oversight of on-range activities
Sam Dearstyne, Megan Gilbert	BLM HQ210 Planning & NEPA support	NEPA review

7.0 Consultation and Coordination

The BLM solicited research proposals on the subject of development and testing methods for long-lasting wild mare fertility control through NOFO L22AS00069 (BLM 2021b) and the parallel RFP for federal agencies. The deadline for submissions was January 31, 2022. Proposals were screened for eligibility, as determined by adherence to NOFO and RFP requirements. A BLM Grants Management Officer worked closely with the BLM's HQ260 Wild Horse and Burro program to organize internal and external review of eligible proposals. External review was conducted by five subject matter experts, none of which were BLM employees, and none of whom had any identified conflicts of interest. The BLM internal review team included the WHB program's research advisory team (described in BLM 2021a), including a liaison to the US Forest Service with veterinary expertise, and to the USDA Animal Plant Health Inspection Service, Veterinary Services branch. The WHB Advisory Board member for WHB Research was not a party to any proposal reviews or discussions, due to a conflict of interest. Additional studies stemming from other eligible research proposals that were responsive to L22AS00069 may or may not also be considered for funding and completion but those would be subject to separate NEPA analysis, if applicable. To protect intellectual property of applicants, the review process is confidential, and all reviewers are subject to non-disclosure agreements.

External Scoping is an option for EAs, per 40 CFR 1501.7, but is not a requirement. Field Office, District Office, and State Office personnel from BLM administrative units that may be involved with proposed research projects have been consulted about potentially required logistical planning. Consultation for the

National Historic Preservation Act (NHPA) or Endangered Species Act was unnecessary because the studies in the Proposed Action are not the kind of undertaking that have the potential to affect historic properties or threatened and endangered species. Studies A and B will take place at the NNCC, in areas where no such impacts are possible. For study C, any such aspects have already been included and analyzed in the EA, FONSI, and decision record for Calico complex wild horse gathering and fertility control, DOI-BLM-NV-W030-2019-0019-EA.

8.0 Public Involvement

On July 20, 2022, this environmental assessment was released to the public for a 30-day comment period on the BLM ePlanning website. A Press Release was issued Wednesday, July 20, 2022, and emailed to interested individuals, agencies and groups. The BLM received 85 comments from the public during the open comment period. The majority of comments came from individuals who did not mention any group affiliation. Comments were also received from submitters who identified themselves as affiliated with: Advocates for Wild Equines National Coalition; American Wild Horse Campaign; Coalition for Healthy Lands, Wildlife, and Wild Horses; National Mustang Association, Inc.; Northern Nevada Safari Club International; Oatman Burros Rehab and Recovery Sanctuary; Oregon Hunters Association; Public Lands Council; Public Lands Foundation; Return To Freedom; Rocky Mountain Elk Foundation; The Cloud Foundation; Wild Horse Education; Wyoming Department of Agriculture; and Wyoming Mustang Institute.

9.0 Appendices

Appendix A – Literature Cited
Appendix B – Comprehensive Animal Welfare Program Standards
Appendix C – Horse and Burro Fertility Control, General Literature Review
Appendix D – Research Proposal for Study A (Oocyte Growth Factor Vaccine)
Appendix E – Research Proposal for Study B (SpayVac PZP Vaccine)
Appendix F – Research Proposal for Study C (iUPOD Intrauterine Devices)
Appendix G – Critical Elements of the Human Environment
Appendix H – Response to Public Comments
Appendix I – Animal Care Protocols