**PPL assessment form**

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| **Title** | **Ralph’s PPL** |
| **Applicant** | **Ralph** |

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PPLNewAssess\_Establishment\_ApplicantSurname\_Date(YYMMDD)\_Inspector initials

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| **Referrals** | |
| **Has been referred internally to [name(s)] –**  **If yes, summarise advice:** | **Yes ☐ No ✅** |
| **Has been referred to ASC**  **If yes, summary of ASC Review:**  **ASRU response to ASC review:** | **Yes ✌︎ No ☐** |
| **Has been referred to external reviewer [named] to consider the following:**  **If yes, summary of external Review:**  Lorermeofnadslfnsoanda FSL CDSI SDFIUNASFLIJFLDSN C  **ASRU response to external review:** | **Yes ☐ No ☐** |

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| **Standards related to introductory details** | |
| * The **title** adequately summarises the project (PPLA2.1) * The whole of the project is for one or more of the **permissible purposes** and the correct permissible purpose(s) have been selected (PPLA2.3)   Information relevant to this standard may also be found in the project plan and protocols  The correct permissible purposes have been selected   * It is clear what **type of animal** will be authorised for use (PPLA3.1) * The project will not use great apes (PPLA3.2.9) * **Teaching** licences are for either: higher education (acquisition of knowledge); or to acquire, maintain or improve vocational skills (acquisition of skills) (PPLA2.7) | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)**  HE SEEMS NICE | |

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| **Standards related to applicant information** | |
| * The applicant: * **Language:** knows enough English to be able to understand the terms and conditions of their project licence (PPLQ1.4) * **Position of authority:** is in an appropriate position of authority to take responsibility for the conduct of the project (PPLQ1.1) * **Area of work:** has expert knowledge in the field relevant to the area of work (PPLQ1.2) * **Species:** has specific knowledge of the biology, physiology and husbandry requirements of the species that will be used (PPLQ1.2) * **Methods and models:** has good knowledge of the methods, animal models and specialised equipment to be used, or access to colleagues who do (PPLQ1.2) * **Experimental design:** has expertise in experimental design, including in statistics where appropriate, or access to such expertise (PPLQ1.2) * **ASPA experience:** has appropriate education and training in designing programmes of work under ASPA (PPLQ1.2) * **3Rs:** has expertise in applying the 3Rs in the relevant field (PPLQ1.2) * **Mandatory training:** meets the mandatory training requirements as shown in the Guidance at Figure 4 and/or there is adequate evidence to support an exemption (PPLQ1.3) * **Funding:** has adequate plans for funding the project (PPLA8) * **Track record:** The applicant or the research group has adequate experience or a track record in the field and in the specific area of work (PPLA8) * **Technical competence:** There is adequate reassurance that there will be users with the required technical competence to carry out the procedures (PPLA1.1.3) | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to project location** | |
| * All named establishments are Licensed User Establishments (PPLA1.1.1) * Each establishment has: * adequate housing, husbandry & care conditions, or an exemption or a lower standard is justified for scientific reasons (PPLA1.1.2) * someone overseeing the work who has appropriate expertise and training (PPLA1.1.1) * appropriate access to veterinary practice in laboratory animal science and/or expertise in wildlife veterinary practice (PPLA1.1.2) * Any movement of animals between establishments, or significant movement within an establishment, is justified and clearly described to minimise adverse impacts on welfare and scientific outcomes ((PPLA1.1.1) * The location of every POLE is adequately specified (PPLA1.2) * The conduct of work at each POLE has a scientific justification (PPLA1.2)   \*\* Do you need to add the standard POLE additional condition? \*\* | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to project plan** | |
| * **Project justification**: the project is justified from a scientific or educational point of view or is required by law (PPLA2.1)   Information relevant to this standard may also be found in the introductory details     * **Prohibited purposes**: the project does not involve testing of offensive weapons or cosmetics, or the development or testing alcohol or tobacco products (PPLA2.3)   **Household products:** (PPLA2.6) the project:   * does not involve testing finished household products * does not involve testing of ingredients primarily intended or expected to be used in household products unless:   + - * + the proposed testing has a regulatory requirement, for example under (UK) REACH (Registration, Evaluation, Authorisation and restriction of Chemicals; and         + there is no other method or testing strategy not involving the use of a live animal, that is recognised under EU legislation and will obtain the required results   \*\* Do you need to add the standard additional condition relating to Household products? \*\*  **Where applications are to provide a service** (PPLA2.5):   * + the nature of the service provision is clear   + the process for deciding whether to accept or reject work is clear * The project’s **aim** suitably defines the area of work (PPLA2.4) * The project's **objectives** are clear, SMART (where possible) and potentially achievable within the specified timeframe (PPLA2.4) * **Duplication:** Any known duplication of procedures is justified. Where data is needed to satisfy EU regulatory requirements, animals will not be used to duplicate data unless it is necessary to protect public health, safety or the environment (PPLA6.3)   For **teaching licences** (PPLA2.7):   * The attendees have a current or future need to carry out scientific work using animals or to perform specialist surgical skills * The learning outcomes cannot be achieved using non-animal alternatives or ex vivo material * There is a satisfactory method of monitoring and evaluating the learning outcomes * The project’s objectives will be reviewed at least once a year to consider the latest alternatives for the 3Rs | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to protocols** | |
| * **Specification of procedures:** The procedures are appropriately specified, justified and relevant to the project (PPLA4.1) * **Appropriate severity classification:** The severity classification for each protocol is in line with Guidance Appendix G (PPLA4.1) * **Species/life stage justification:** The species and life stages are relevant and adequately justified (PPLA3.1) * **Continued use** of animals, either from or onto other protocols or projects, is reasonable and appropriately specified (PPLA4.1)   \*\* Have you provided all necessary authorisations for continued use onto and off protocols, and also from any other (expiring) project? \*\*   * **Anaesthesia/analgesia:** Planned use of anaesthesia, analgesia and other pain-relieving methods is justified and relevant (PPLA6.4)   Information relevant to this standard may also be found in the NMBA section of other considerations   * **Killing methods** are either appropriate methods as defined by ASPA 15A or are scientifically justified and appropriately specified (PPLA5.1) * **Humane endpoints**: The use of humane endpoints is justified and relevant (PPLA6.4) * **Experimental/statistical design:** The experimental or observational strategy and statistical design to minimise numbers, harms and environmental impact are appropriate and adequate (PPLA6.1)   Information relevant to this standard may also be found in the project plan   * **Suffering justification:** Any form of animal suffering, from birth to death, is justified and relevant (PPLA6.4)   Information relevant to this standard may also be found in the project location, use of animals and other considerations  **Licences for work that needs to satisfy regulatory guidelines**  (Information relevant to these standards may also be found in the project plan)   * **The regulatory guidelines or framework(s**) to be met are clear (PPLA2.6) * **Alternatives:** There are no satisfactory non-animal alternatives. Where non-animal alternatives are accepted by the Regulator they are used (PPLA2.6) * **3Rs:** There is a commitment to follow the most refined tests using the minimum numbers of animals that will satisfy the Regulator(s) (PPLA2.6) * Where testing is for **non-EU countries**, the method used is the most refined, uses fewest animals of the least sentient species and provides a scientific result that is recognised as valid by EU legislation (PPLA2.6)   \*\* Have you added the standard additional condition for regulatory studies? \*\*   * For all **batch quality testing** using live animals, the substance or product to be tested is named and a scientific justification provided (PPLA2.6)   \*\*Do you need to add the standard additional condition relating to batch testing?\*\* | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to use of animals** | |
| * The animal’s **origins** are justified and relevant to the project (PPLA3.1):   + Schedule 2 species are purpose bred or there is a scientific justification for using Schedule 2 species that are not purpose bred * Non-Schedule 2 species are from a source that can provide animals of a sufficient quality to produce satisfactory outputs   \*\*Do you need to add the standard additional condition to disapply PPL SC13(d)? \*\*  **Stray animals** will not be used (PPLA3.2.8)  **Cats, dogs and equidae** are used only if there is scientific justification that the project’s aim cannot be achieved without them, or by using another species which it is not practicable to obtain (PPLA3.2.1)  **Non-endangered NHPs** are used only if there is a scientific justification that the project’s aim cannot be achieved without them and the project is for one of the following permitted purposes (PPLA3.2.2)   * translational or applied research for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * the development, manufacture or testing of the quality, effectiveness and safety of drugs for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * basic research * research aimed at preserving the species of primate being used   **Endangered NHPs** are used only if there is scientific justification that the project’s aim cannot be achieved without them and the project is for one of the following permitted purposes (PPLA3.2.3):   * translational or applied research for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * the development, manufacture or testing of the quality, effectiveness and safety of drugs for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * research aimed at preserving the species of primate being used   **Marmosets** must be the offspring of marmosets bred in captivity or from a self-sustaining colony unless there is scientific justification that the aim of the project cannot be achieved without them (PPLA3.2.5)  \*\*If marmosets are not from a self-sustaining colony, have you applied the necessary additional condition?\*\*  **Endangered animals (not NHPs)** are used only if there is scientific justification that the project’s aim cannot be achieved without them and the project is for one of the following permitted purposes (PPLA3.2.4):   * translational or applied research for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants * the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs or feedstuffs for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man, animals or plants; or the assessment, detection, regulation or modification of physiological conditions in man or the improvement of the welfare of animals reared for production purposes * research aimed at preserving the species of animal used   **Animals taken from the wild** are used only if:   * there is scientific justification that the project’s aim cannot be achieved without them (PPLA3.2.6) * there is adequate competence to undertake decision making about the health and welfare of animals taken from the wild (PPLA1.1.3)   \*\*Do you need to add the additional condition to disapply PPLSC13(b)?\*\*  \*\*Have you added the standard additional condition to minimise suffering for wild or feral animals?\*\*  **Feral animals** are used only if there is scientific justification that the project’s aim cannot be achieved without them and a study is essential to protect the health or welfare of that species, or to avoid a serious threat to human or animal health or the environment (PPLA3.2.7)  \*\*Do you need to add the additional condition to disapply PPLSC13(a)?\*\*  \*\*Have you added the standard additional condition to minimise suffering for wild or feral animals?\*\* | |
| **Does the application satisfactorily meet these standards?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to other considerations** | |
| It is clear why **ACHM** classified as Category 2 or 3 by the Academy of Medical Sciences is necessary (PPLA3.2.10)  **NMBAs** (PPLA4.2)   * If requested, **NMBA**s are necessary for the project * The proposed anaesthetic and monitoring regime is appropriate * There are enough competent people to administer NMBAs and monitor the correct level of anaesthesia, including over a long period of time, if necessary * The emergency routine to cater for hazardous events is adequate to safeguard animal welfare   \*\* Do you need to add the NMBA Additional Condition? \*\*  **Re-homing** (PPLA5.2)  Where animals are to be re-homed:   * their state of health will allow them to be re-homed * re-homing poses no danger to public health, animal health or the environment * there is an adequate scheme for ensuring socialisation on being re-homed * any other necessary measures to safeguard wellbeing on being re-homed are specified (PPLA5.2)   \*\* Have you provided the necessary authorisation for re-homing? \*\*  **Setting animals free** (PPLA5.3)  Where animals are to be set free:   * their state of health will allow them to be set free * setting them free poses no danger to public health, animal health or the environment * there is an adequate scheme for ensuring socialisation on being set free * any other necessary measures to safeguard wellbeing on being set free are specified * there is adequate competence to undertake decision making relating to their health and welfare (PPLA1.1.3) * If they have been taken from the wild, there is either an appropriate programme of rehabilitation or rehabilitation would be inappropriate (PPLA5.3)   \*\* Have you provided the necessary authorisation for setting free? \*\*  **Commercial slaughter** (PPLA5.4)  Where farm animals are to be sent to a commercial slaughterhouse:   * The animal will be appropriately identified and transported in accordance with the relevant legislation * The animal’s state of health meets commercial requirements for health and hygiene, including substance withdrawal times * commercial slaughter will pose no danger to public health, animal health or the environment * pending transport to the slaughterhouse the animal is kept in an appropriate social group under the supervision of the NVS * Any other necessary measures to safeguard wellbeing are specified * there is adequate competence to undertake decision making relating to their health and welfare (PPLA1.1.3)   \*\*Have you added the standard additional condition to authorise sending to commercial slaughter?\*\*  **Re-using animals** (PPLA6.5)   * The proposed re-use, taking account of accumulative effects, strikes an appropriate balance between reduction and refinement * Re-use will not significantly affect the scientific outcomes   Information relevant to this standard may also be found in the protocols   * There are adequate reassurances that the requirements of ASPA S14 are met   \*\* Have you added all necessary authorisations for re-use? \*\* | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)**  CHECK ANIMALS ARE NOT KEPTALIVE AND RE-USED. FATE SECTION IN NTS WILL NEED TO BE REVIEWED | |

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| **Standards related to the 3Rs** | |
| * Reasonable steps have been taken to find alternatives, for example NC3Rs or Norecopa (PPLA6.2) * The project’s objectives justify the use of protected animals and could not be achieved using non-animal alternatives (PPLA6.2)   Information relevant to this standard may also be found in the project plan   * There is a reasonable explanation for the numbers of animals to be used (PPLA6.3) * The project will use the least sentient species and life stages to achieve its objectives (PPLA6.4)   Information relevant to this standard may also be found in the protocols   * Methods to replace, reduce and refine are appropriate and adequate (PPLA6.1)   Information relevant to this standard may also be found in the protocols and project plan | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to the Non-technical summary** | |
| The NTS (PPLA7):   * is written in non-technical language * includes adequate information on the project’s objectives, predicted harms and benefits and the number and type of animals * demonstrates appropriate compliance with the principles of the 3Rs * contains no intellectual property or confidential material * contains no information from which the identity of the applicant or group could be ascertained | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Standards related to the application as a whole** | |
| * There are no real or perceived conflicts of interest (PPLQ1.1) * The application covers a single, coherent project (PPLA2.1) * The application is endorsed by the NPRC at all establishments specified, and the AWERB(s) have been consulted (PPLA1.1.1) * The programme of work is designed to enable the procedures to be carried out in the most humane and environmentally sensitive manner possible (PPLA2.1) | |
| **Are you satisfied these standards have been fulfilled?** | **Yes ☐ No ☐** |
| **Reasoning or clarification (optional)** | |

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| **Harm-benefit analysis** | |
| **Analyse the likelihood of success**  Consider standard PPLA8:   * The proposed species, models and methods are likely to achieve the stated benefits * There is a clearly defined plan of work, including information about choice of methods/experimental design/species/animal model and clear, realistic objectives * There are adequate plans for funding the project * There are appropriate facilities, equipment, skills and services for the proposed work * There are appropriate plans to validate new or novel methodology and to acquire technical competence * The outcomes are deliverable in the timeframe of the project * The work is timely and is scientifically sound * The applicant or the research group has adequate experience/ track record in the field and in the specific area of work * There is an appropriate publication plan, where appropriate   Comment on the quality of outputs eg GLP | Free text |
| **Analyse the expected benefits**  Consider:   * Direct or Project-Related Benefits * Indirect benefits * Field-related benefits * Cross-field benefits * 3Rs benefits | Free text |
| **Analyse the nature of the harms**  Consider:   * Contingent harms * Project-Related Harms * the types of procedures * the frequency of procedures * the duration of procedures * the proportion of animals likely to reach each level of severity within a protocol * the nature, severity and likelihood of each adverse effect and the proportion of animals predicted to be affected * the origin, species, strain and age/stage of development of animals being used * the number of animals * the fate of each animal (e.g. humane killing, re-use, rehoming) * are animals killed? If so, by what method and how many? * are animals to be re-used? * Cumulative Effects * Mitigation/Amelioration of Harm * Identify the major and typical harms * Consider potential alternatives * Consider potential refinements * Consider proposed numbers   Include specific advice from referrals relating to 3Rs issues or to models/methods | Free text |
| **Outcome of HBA:**  **How do the potential benefits justify the harms?** | Free text |

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| **Setting an RA** | |
| **Do you need to set any additional RA dates?**  **RA will automatically be set on expiry for projects using NHPs, cats, dogs, Equidae, endangered animals and procedures classified as severe. You will need to set an RA for teaching licences and projects** raising important animal welfare or ethical concerns, novel or contentious issues or societal concerns  **If yes, why?** | **Yes ☐ No ☐** |
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| **Other Additional conditions** | |
| I have added the following additional condition(s):  Rationale for addition other additional conditions: | **Yes ☐ None ☐** |

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| **Final decision** | | |
| I am clear about what the applicant is applying to do and understand the application. I have considered all relevant matters and assessed the likely benefit (potential benefit, likelihood of producing satisfactory results, suitability of applicant) and expected severity of the work described in the application. | | |
| The expected harm to protected animals in terms of pain, suffering, distress and lasting harm is justified by the expected outcome, taking account of ethical considerations, the likelihood of producing satisfactory results and the expected benefit to humans, animals or the environment.  A licence granted on the terms above will satisfy the relevant criteria of the Animals (Scientific Procedures) Act 1986. | | **Yes ☐ No ☐** |
| **Licence granted with all additional conditions and authorisations applied**  **If refused, list the [PPL assessment standard(s)](https://ukhomeoffice.sharepoint.com/:w:/s/PROC782/Ecyq4EqSPklGnMX1xw6jtBsB5rKvCJi1MsElWp5sT4M-Ag?e=uHhyZZ) that have not been met:**  *Eg PPLA9 The Harm-benefit Analysis*  *PPLA3.2.9 The project will not use* ***great apes***  **Summary rationale for refusal for the ‘Notice of Intent to Refuse’:** | | **Granted ☐**  **Refused ☐** |
| **NTS:**  The NTS is suitable to be published  **Action to be taken if No:** | | **Yes ☐ No ☐** |
| **BF file to [DATE] to check for receipt of [report/certificate etc]** | | **Yes ☐ N/A ☐** |
| **Inspector name:** |  | |
| **Date:** |  | |

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