The following checklist summarizes QAPP requirements for projects involving the use of animal subjects (also known as in-vivo research). More comprehensive guidance on developing QAPPs for research projects is provided in the EPA/240/R-02/009 report titled “Guidance for Quality Assurance Project Plans ([EPA QA/G-5](https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf)).” The completed checklist will be entered into QA Track with the approved QAPP by the QA Manager when final.

## B.1 EXPERIMENTAL DESIGN

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Requirement** | **Notes** |
|  |  |  | Discuss the choice of animal subjects to be tested, including ACUP/LAPR references, if applicable in addressing the study objectives. (ACUP = Animal Care and Use Protocol, previously known as the LAPR = Laboratory Animal Protocol Report. These documents address the regulatory animal care and use ethics requirements.) |  |
|  |  |  | Discuss the choice of chemicals, materials, or other stressors to be tested in addressing the study objectives. |  |
|  |  |  | Discuss independent variables to be manipulated. |  |
|  |  |  | Discuss dependent variables to be measured. |  |

## B.2 METHODS AND EXPERIMENTAL DETAIL

| **Yes** | **No** | **N/A** | **Requirement** | **Notes** |
| --- | --- | --- | --- | --- |
|  |  |  | Describe the method for determining test group treatment, number, and size (dose limits; power calculations). |  |
|  |  |  | Describe the method for test group assignment and identification for individual animal subjects (randomization; tagging, group housing). |  |
|  |  |  | Describe study controls (blinding; standard curves; positive/negative controls; control, sentinel, and sham animals, etc.). |  |
|  |  |  | Provide details of sample collection, identification, storage, analysis etc. |  |
|  |  |  | List and attach all operating procedures or protocols and ensure that they include adequate quality control. |  |
|  |  |  | Describe the procedures to be used for any activities that are not covered by existing operating procedures or protocols. Ensure that appropriate quality control is included. |  |

## B.3 EQUIPMENT AND SUPPLIES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Requirement** | **Notes** |
|  |  |  | List major equipment (make, model). |  |
|  |  |  | List critical supplies (name, source, amount, expiration dates if any). |  |

## B.4 DATA COLLECTION AND ANALYSIS

| **Yes** | **No** | **N/A** | **Requirement** | **Notes** |
| --- | --- | --- | --- | --- |
|  |  |  | List and describe (analog, electronic, etc.) datasets to be collected . |  |
|  |  |  | Describe data verification procedures used to ensure reporting of accurate data |  |
|  |  |  | Describe planned statistical analysis following guidance of: <https://intranet.ord.epa.gov/nheerl/cop-statistics-study-design-experimental> |  |

QAPP Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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