

Outline for the LETTER OF INTENT

A Letter of Intent (LOI) submitted to the Animal Model Qualification Program is a stand-alone submission package and should contain the following information in the format as outlined. The document should be in the form of a searchable pdf file and information sources (e.g., publication, website) should be cited using in-text numbers and a reference list at the end of the document.

Note that the italicized information will be posted publicly under Section 507 of the Federal Food, Drug, and Cosmetic Act, which was created by Section 3011 of the 21st Century Cures Act. The information submitted in these sections will be copied verbatim and, therefore, should read as a stand-alone section and should not refer to other sections of the LOI that will not be posted publicly.

Requestor Institution Information

1. *Name*
2. *Address*
3. *Phone number*
4. *Fax number*

Primary Contact Information

1. Name
2. Role (e.g., Project Manager, Consultant, Primary Investigator)
3. Address
4. Phone number
5. Phone number (alternate)
6. Fax
7. Email address

Alternate Contact Information (optional)

1. Name
2. Role (e.g., Project Manager, Consultant, Primary Investigator)
3. Address
4. Phone number
5. Phone number (alternate)
6. Fax
7. Email address

Key Elements

1. *Title of animal model qualification project*
2. *Proposed context of use statement*
3. *Animal species*
4. *Challenge agent*
5. *Route of exposure to challenge agent*
6. *Intended use in therapeutic development (i.e., pre-exposure, post-exposure, mitigation, treatment)*
– choose all that apply

Background Information

1. *Introduction (500 words) – This should be in abstract form. Describe the human disease or condition and the corresponding animal model. Include the following information:*
 - a. *The etiologic and challenge agents*
 - b. *Historical information regarding the existence of animal models for this disease or condition (e.g., there are no models available, there are multiple models)*
 - c. *The importance of developing this animal model*
 - d. *The intended use of this animal model in drug development*

2. Human disease or condition (1000 words) – This should be a brief summary of the human disease or condition, including the identification of key features. Include the following information if available; identify gaps in understanding the human disease or condition:
 - a. Etiologic agent
 - b. Route(s) of exposure
 - c. Characteristics of the disease or condition (e.g., time course, signs/symptoms, gross and microscopic lesions)
 - d. Justification for the use of the Animal Rule regulatory pathway for the approval/licensure of drugs for this disease or condition

3. Animal model (1000 words) – This should be a brief summary of the proposed animal model. Include the following information if available:
 - a. Characteristics of the animal including but not limited to genus/species/strain, sex, age, and weight
 - b. Characterization of the challenge agent
 - c. Method/route of exposure
 - d. Characteristics of the disease or condition (e.g., time course, signs, gross and microscopic lesions)
 - e. Primary and secondary endpoints
 - f. Proposed types of data to be collected (e.g., observational, clinical chemistry, hematology, pathology)

4. Comparability of the key features of the human disease or condition and the proposed animal model – Include discussion of similarities and differences. This information is best presented in a table.

Characteristics of the Data

1. Indicate the type of data that will be submitted to support the proposed context of use. Choices include:
 - a. Data from completed studies
 - b. Data from planned studies
 - c. Combination

2. Studies submitted to support qualification may be subject to FDA inspection. Will data submitted be from studies available for inspection? Choices include:
 - a. Yes
 - b. No
 - c. Combination (i.e., some data available for inspection and some data are not)
 - d. Unknown

3. Will data submitted be from studies conducted in accordance with GLP regulations? Choices include:
 - a. Yes
 - b. No
 - c. Combination

4. Will data submitted be from studies conducted outside of the United States? Choices include:
 - a. Yes
 - b. No
 - c. Combination

Additional Sections (as needed)

1. Questions for FDA
2. References
3. Attachments – Attach copies of most relevant publications (maximum 10)
4. Appendices – Please note that LOI submissions should not include protocols or study results