



## Important Information for Protocols that had Full Committee Review

If your protocol underwent IACUC Full Committee Review (FCR), the following legal requirements may apply to you. Examples of protocols with specific concerns that require additional attention include research that involves pain and distress, prolonged restraint, cancer studies, and humane endpoints or euthanasia as part of a procedure.

**Key components** that such protocols must include and **for which records must be kept** are information demonstrating:

1. Adequate monitoring,
2. Criteria for timely intervention,
3. Criteria for removal from study or euthanasia.

The federal Animal Welfare Act (AWA) requires that the **Principal Investigator** keep records for protocols involving pain and distress that clearly document monitoring, interventions, and removal or euthanasia. Records must be kept for **two years** after the completion of the protocol. In addition, federal Good Laboratory Practice (GLP) regulations require that detailed records be kept for all pre-clinical research.

Records must be maintained and readily available to Federal inspectors and to IACUC, DAR or AACUP veterinary staff. Advance notice is not required for inspection so it is important that records be up to date and readily located.

Developing and preparing score sheets that are species- and procedurally-specific for each protocol is an AAALAC recommended approach for pain and distress record keeping.

Key resources to help individuals recognize and manage pain and distress are published by the National Resource Council, [Recognition & Alleviation of Pain and Distress in Laboratory Animals](#), or the revised versions, [Recognition & Alleviation of Distress in Laboratory Animals](#) and [Recognition & Alleviation of Pain in Laboratory Animals](#) which provides appendices with species specific signs. Also, the Institute of Laboratory Animal Resources (ILAR), [Definition of Pain and Distress and Reporting Requirements for Laboratory Animals](#).