

## Notification Plan for Animal Study Proposal Renewals and Annual Reviews

Animal Study Protocols undergo two types of continuing review: Full Renewal and Annual Review.

### Renewals

The full Renewal is a complete revision of the protocol and is completed every 3 years. This revision is required by the Public Health Service (PHS) Policy (IV,C,5) that states that “the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including complete review in accordance with IV,C,1-IV,C,4 at least once every three years.”

A renewal is a complete revision of the protocol that incorporates all existing and proposed animal experiments for the next 3 years.

- Renewals will be scheduled to be reviewed at an ACUC meeting two months prior to the expiration date. The first draft of the renewal is due to the ACUC office 3 months prior to the expiration date.
- At **Two months** prior to the scheduled ASP submission deadline, an email message is sent to the PIs At **four weeks** prior to the applicable ASP submission deadline, a reminder e-mail is sent to the PI
- **One** week prior to the applicable ASP submission deadline, the PI will receive a phone call to address any last minute concerns or computer related issues.
- Any studies that still have not been renewed or annually reviewed by the applicable ASP expiration date will be inactivated immediately. All animals housed on this study will become property of the ACUC and no data collection or experimental procedures will be conducted. Animal husbandry and care will continue to be provided by the facility staff.
- If any PI continues to seek data collection or to perform experimental procedures on animals placed in an inactive status before a renewal or annual review has been approved by the ACUC, the matter will be forwarded to the ACUC for necessary action.
- The notification of the ASPs inactive state will be issued to the PI, the facility manager, and the Lab/Branch Chief.

The list of meeting dates and submission deadlines can be found on-line at the following site:

<https://ncifrederick.cancer.gov/lasp/acuc/bethesda/Default.aspx>

## Annual Reviews

The Annual Reviews are required by the Animal Welfare Act Regulations (2.31,d,5) that state that “the IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually.”

The Annual Review is a brief questionnaire to ensure that the protocol accurately reflects the study being performed.

- Annual Reviews are due to be reviewed by the full ACUC at a convened meeting that falls on the same month the protocol was approved. For example:
  - ASP-123 was approved 6/8/2015
  - First Annual Review will need to be on the agenda for the 6/2016 and the 6/2017 ACUC meetings.
- Reminders for the Annual reviews are sent via iRIS to the PI and study contact automatically.
- In addition to the automatic reminders from iRIS, the ACUC office sends reminders one month before the meeting on which they will be reviewed as well as approximately one week before the meeting.

**Sample Workflow for 1 meeting.**

Month 1						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4 First e-mail sent to investigators regarding due date.	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Month 2						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2 e-mail sent to investigators regarding due date.	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30 Investigators called to offer assistance and remind of deadline			

Month 3						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7 First Draft items due for ACUC meeting	8	9 Items sent for Pre- Review	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26 Revised items due to ACUC office	27	28 Packets sent to ACUC Members	29	30	

Month 4						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	3	4	5 ACUC Meeting	6	7 Outcome letters sent to investigators	8
9	10	11	12	13	14 Response due from investigators (flexible deadline)	15
16	17	18	19	20	21 ACUC signoffs due	22
23	24	25	26	27	28 Facility signoff due  Approved	29
30						