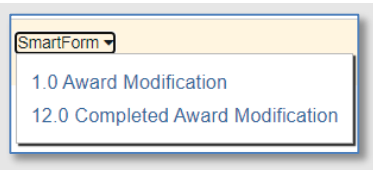## UFIRST Award Compliance Modification

Award Compliance Modifications are entered in UFIRST to update Award or Project level compliance (IACUC, IRB), including adding a new protocol or editing an existing protocol. A compliance modification type may be selected in companion with other modification actions. A modification is not needed to update the expiration date of a protocol already associated with the award in UFIRST; as long as the protocol number is the same, UFIRST will automatically update with the new expiration date within 48 hours of protocol renewal. In general the only times a compliance modification would be entered would be to link a new protocol for a project which had been previously operating with an exception or to add a new protocol to a program where new activities were added and the sponsor has approved the change in scope.

1. From the UFIRST Award workspace, *click* "Create Award Modification" under My Activities and then *click* "Ok" in the window that pops up.

    a. UFIRST will only allow one modification (MOD) to be entered at a time and will display an error if a MOD is currently in progress. If a MOD is already in progress, you may be able to add to the current MOD. Skip b. and proceed to c.
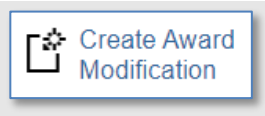
    b. Once the new MOD record appears in the list on the "Modifications" tab, *click* on "SmartForm". A drop down menu appears. *Click* on "1.0 Award Modification" to navigate to the first page of the SmartForm. The MOD is now in Pending Responsible Unit Edits state.

    c. On page 1.0, under field 2.0 "Select Modification Type", *mark the box* for "Compliance (IRB, IACUC)".

    d. On page 1.0, under field 3.0 *enter* 'INTERNAL' for the Award ID for the modification if internally driven. If the sponsor updated the award ID, update according to DSP guidance. Under fields 4.0 and 5.0 *attach* related modification documents, if applicable. Any supporting information (such as an email history) should be placed under field 5.0.

    e. On page 1.0, under field 6.0a, *enter text* under "Brief Description", providing as much detail as you can about the who, what, when, where, how and why behind this modification. *Click* "Save" at the bottom of the page and then *click* "Continue" to advance.
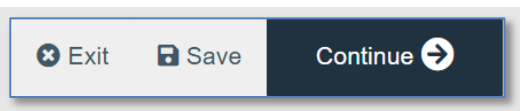
    f. On page 2.0, *relate* associated proposals, agreements, or awards as applicable. *Click* continue to advance.

g. On page 9.0, **update** fields as necessary. If "Human Subjects Including Human Data or Tissue" or "Live Animal Vertebrates" was marked "no" but should be marked "yes", or is "yes" but should be marked "no", please work with the DSP Owner assigned to the MOD as only those with the DSP Manager role are able to change the answer. If no DSP Owner is assigned to the MOD, please email ufawards@ufl.edu and include a copy of the UFIRST record number.

h. DSP will review the MOD to ensure that the title and funding source of the protocol(s) entered in MyIACUC, goIACUC or MyIRB match the award. If the title or funding source do not match, DSP will return the MOD to Pending Responsible Unit Edits state until the discrepancy is addressed.

i. After "yes" is selected box 1.0 pops up, **click** add, and a slide-in appears from the right side of the page. Question 1.0 allows you to identify the correct IRB/ IACUC approval number.

j. After the correct IRB/ IACUC protocol is linked, move to question 2.0 and click the appropriate check box to associate the IRB with the correct project.

k. After selected, **click** "ok" if done, **click** "ok and add another" if another IRB/ IACUC number needs to be listed, or **click** "cancel" if no change is desired.

l. The Animal waste, unfixed animal tissue, or body fluids question is required and must be answered before the MOD can move forward.

m. **Click** continue when done adding protocols.

n. On page 12.0, **enter** the effective date of the modification as the start date of the award (see award workspace), or the start date of the applicable change (if Sponsor driven) **Click** "Finish".

2. **Complete** the ''Submit for Review' activity.

3. The modification is now in DSP Review. If Sponsor **_approval is required_**, DSP will facilitate communication to the sponsor and will place the MOD in "Awaiting Sponsor Approval" state.

4. When a response is received:

    a. If the Sponsor denies the request, the Unit and PI will be notified of this denial by DSP before further processing the MOD. After all parties are notified, unless further discussion needs to occur, DSP will mark the MOD as "Sponsor Denied." The AWD Modification will now be complete and in a state of *Sponsor Denied*.

    b. If the Sponsor approves the request, DSP will mark the MOD as "Sponsor Approved," then send the MOD to Contracts & Grants (C&G) Accounting for approval.

5. C&G will review and finalize the modification. If required, C&G and/ or DSP will engage the Primary Unit Admin Contact to resolve any issues. Once C&G review is complete, the AWD MOD will enter a state of *Completed* in UFIRST.

Appendix I   Protocol Entry format:

Source of Approval	Format of Approval Number	Sample	Notes
myIRB	YYYYnnnnn	201801234	YYYY is year, nnnnn padded sequence number
Legacy IRB	YYAnnnn	11H0123	Historical IRB system numbers; may still be used when protocol is older IRB-02 reviewed protocol. Where YY is year, A is the IRB letter (H,J,U) and nnnn is a padded sequence number.
External Protocols (IRB/IACUC)	EPnnnnnnn	EP1600028	External institution's IRB/IACUC review has been deemed acceptable and appropriate for UF use. IACUC Only: external protocols are the MOU with a partnering domestic institution.
myIACUC	YYYYnnnnn	201701001	YYYY is year, nnnnn is padded sequence number
goIACUC	YYYYnnnnnnnn	202100000010	YYYY is year, nnnnnnnn is padded sequence number
Legacy IACUC	Nnnn	N079; VA91	Historical IACUC system numbers.
WIRB – Gainesville/Jacksonville	Nnnnnnn	1046570	WIRB is the ONLY Central IRB that UF researchers may submit their research to; limited to industry sponsored trials involving FDA regulated drugs or devices.

NOTE: "Ceded" IRBs are entered in the myIRB system and have an approval number that starts with '0000'.