Proposal Compliances

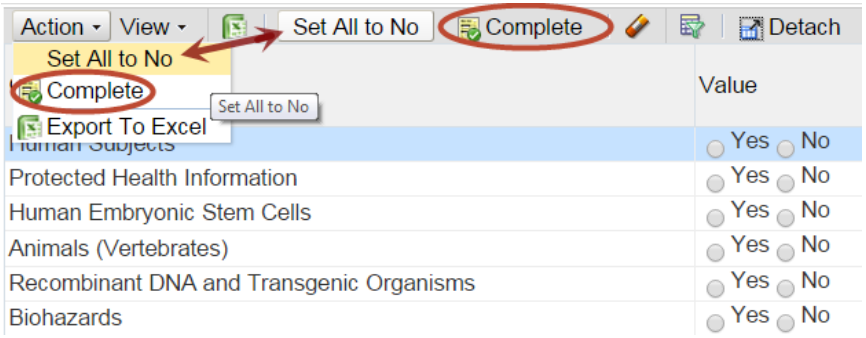
This screen is used by Proposal Administrators and Principal Investigators to maintain proposal compliance data.

The "Compliance Item List" lists all compliance items that must be designated as either being applicable or not applicable to the proposal. The default value for each item is null.

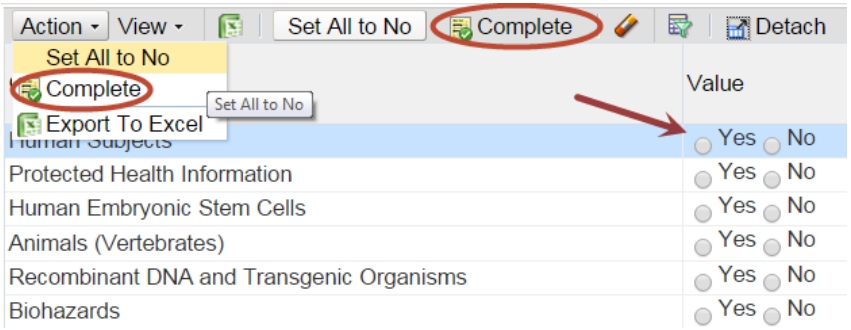
The "Value" column contains a Yes/No radio button, which is used to indicate either:

- Yes – this compliance item applies to this proposal
- No – this compliance items does not apply to this proposal

To set all items to No, click the "Set All to No" icon, or you can click on Action then Set All to No. Be sure to click COMPLETE via the icon or the Action link.

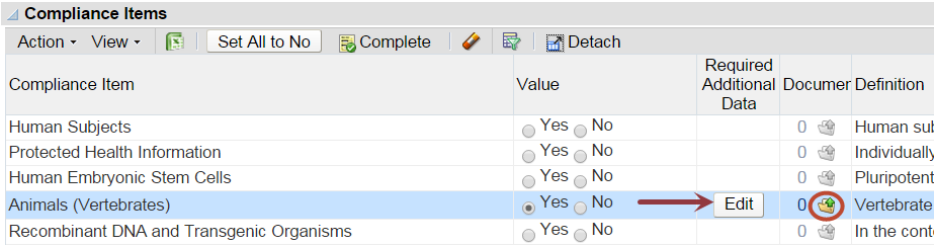


To select a value for an item, click the appropriate Radio Buttons.



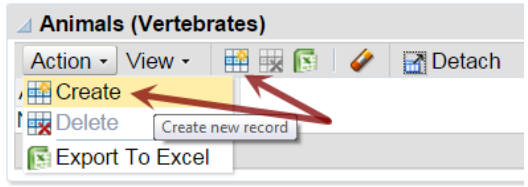
Required Additional Data & Required Documents

The required additional data Edit button is enabled whenever you select Yes for a compliance item that needs additional information entered. For example, if you select Yes for item "Animals (Vertebrates)", the Edit button will become enabled.



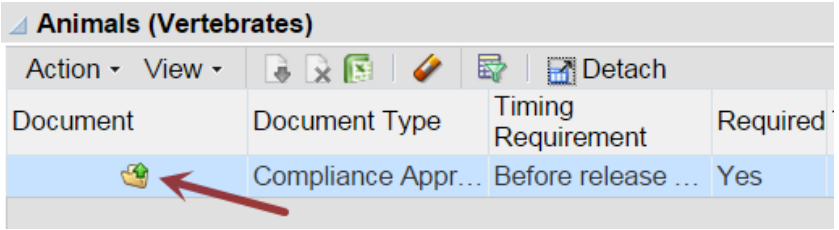
To add the required additional data, click the Edit button which will open the Proposal Compliances – Required Additional Data screen.

Then select Action>Create from the Action/Icon Toolbar or click the Create new record icon.



Selecting Yes for a compliance item will enable the folder icon located in the Required Documents column.

To upload documents, click the button, which will open the Proposal Compliances – Required Documents screen. To upload the document, click the folder icon, browse and select the appropriate file, then click upload.



Compliance Items Definitions

Human Subjects - Human subject/human participant research is applicable when the proposed research involves development, testing and/or evaluation of a living individual about whom a professional or student shall be conducting research by collecting data (through physical procedures which manipulate the individual or his/her environment or through communication via interpersonal contact) and the data contains identifiable and/or private information. Includes surveys

Protected Health Information - Individually identifiable health information transmitted or maintained in electronic or any other form or medium that is held by a "covered entity:. 45 CFR 160.103.

Human Embryonic Stem Cells - Pluripotent stem cells derived from early stage human embryos, up to and including the blastocyst stage, that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. http://stemcells.nih.gov/info/glossary.asp

Animals (Vertebrates) - Vertebrate animals used for research, testing, and teaching. This includes: live vertebrates, animal tissue, blood and sera, animal carcasses and field studies that disturb the natural habitat of the animal.

Recombinant DNA and Transgenic Organisms - In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Biohazards - Any pathogens or potential pathogens of human, animals or plants; materials potentially containing human pathogens (including human blood, tissue and cell lines; non-human primate blood, tissue and cell lines), recombinant DNA (and RNA) including creation or use of transgenic plants and animals and/or biological toxins.

Select Agents - Select agents are pathogens or biological toxins which have been declared by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the "potential to pose a severe threat to public health and safety". A list of select agents may be found at: http://www.selectagents.gov/

Involves use of Biosafety Level 3 (BSL-3) Facility BSL3 non-select agent/ABSL3 - Work with infectious agents that require biosafety level 3 facilities.

Renovations to Facility - As defined in TAMUS Policy 51.01, Capital Planning (http://policies.tamus.edu/51-01.pdf).

Planned Environmental Release of Infectious, Hazardous or Genetically Modified Organism - Release into the environment of infectious material, hazardous chemicals, radioactive material or genetically modified organisms.

Radioactive Materials/Radiation Producing Devices - Radioactive Material – solid, liquid or gaseous material containing atoms with an unstable nucleus, which disintegrates by the spontaneous emission of charged particles and/or photons, including radioactive isotopes with atomic numbers of 3 through 105. This specifically includes accelerator- produced, reactor-produced, naturally occurring radioactive material (NORM), technically enhanced material (TENORM), and exempt sources. This also includes any radioactive material that will be used at locations away from the main university campus in College Station or at sea.

Radiation Producing Device (RPD) – an electrical device which is capable of producing ionizing radiation. This specifically includes x-ray machines, accelerators, neutron generators, and x-ray diffraction devices. Some RPDs may also contain one or more radioactive sources.
https://ehsd.tamu.edu/Pages/RadSafety.aspx

DEA Controlled Substances - A controlled substance is generally a drug or chemical whose manufacture, possession, and use are regulated by a government. DEA Controlled substances as listed at:
http://www.deadiversion.usdoj.gov/schedules/index.html

Regulated Hazardous materials -

Explosives - A chemical substance that contains a great amount of stored energy that can produce an explosion, a sudden expansion of the material after initiation by heat or shock, accompanied by the production of heat and pressure. Explosives can be purchased or manufactured. Explosives are

categorized by USDOT as a Class 1 hazardous material, with Divisions of 1.1 through 1.6, depending on specific properties of the material. The use of explosive materials in research may require obtaining a license from the Bureau of Alcohol, Tobacco and Firearms (ATF), may institute specific reporting to the Department of Homeland Security (DHS) and will require compliance with specific fire code provisions, all of which will require several months of lead time.

Scientific Diving - Scientific Diving is any underwater diving performed by individuals necessary to and part of a scientific, research, or educational activity, in conjunction with a project or study under the jurisdiction of any public or private research or educational institution or similarly recognized organization, department or group. Diving for recreational purposes while on business travel for the Texas A&M University System does not constitute scientific diving. https://ehsd.tamu.edu/Pages/SciDivingSafety.aspx

Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP)/Good Clinical Practices (GCP) if required by sponsor - FDA regulations governing non-clinical research (GLP; 21 CFR Part 58), clinical trials (GCP; 21 CFR Part), and manufacturing (GMP; 21 CFR Part 210, 211, 225, and 226).

Nepotism - As defined in TAMUS Policy 33.03, Nepotism (http://policies.tamus.edu/33-03.pdf)

Firearms - As defined in TAMUS Policy 34.06.02, Weapons (http://policies.tamus.edu/34-06-02.pdf)

Export Control –

- Pre-publication Approval Required by Sponsor
- Sponsor Restrictions on Participation of Non-US Persons
- International Collaboration: An international collaboration is a research relationship with another foreign researcher or sponsor who is based or head quartered outside the U.S.
- Project Performed at a Non-US Location: http://www.bis.doc.gov/licensing/exportingbasics.htm
- Items to be Shipped to a Non-US Destination: http://www.bis.doc.gov/licensing/exportingbasics.htm
- Equipment, software or technology used in the project is designed/modifiable for military use or outer space - https://www.pmddtc.state.gov/regulations_laws/documents/official_itar/ITAR_Part_121.pdf
- The proposed research could be used in the development of weapons of mass destruction. https://www.pmddtc.state.gov/regulations_laws/documents/official_itar/ITAR_Part_121.pdf
- The proposed research contains source code for 128-bit encryption software or mass-market encryption products - https://www.bis.doc.gov/index.php/policy-guidance/encryption

Conflict of Interest - As defined in TAMUS Policy 15.01.03 (http://policies.tamus.edu/15-01-01.pdf).

Responsible Conduct of Research - NIH requires RCR training for anyone funded on their training grants. NSF requires RCR training for students at any level supported by NSF funding.

Intellectual Property Anticipated to be Developed – Intellectual property is anticipated to be developed.

Questions?

For proposal questions, contact the Proposal Administrator listed on the General Info Screen.

For technical assistance, email maestro@tamus.edu or call 979-458-8741.