# What Do I Need to Submit with my Protocol?

\* = required with submission

#### **New Protocol**

- Protocol form (create New Protocol Application and submit online)\*
- Approved Radioisotopes Form (protocol section L.2a; if protocol includes use of radioisotopes)
- Approved Chemical Safety Form(s) for any carcinogen, toxin, hazardous material, or substance with unknown properties (protocol sections L.3a and b)
- Procedural Experience and Contact List (PECL) for all animal users and all animal procedures on protocol
- Signed DFCI adjuvant policy (policy #P008) if protocol includes research use of adjuvants
- Signed DFCI diphtheria toxin policy (<u>policy #P038</u>) if protocol includes use of diphtheria toxin in live animals

#### Amendment

- Completed Amendment form
  - o Amendment Form A if change in PI
  - o Amendment Form B if adding personnel other than PI
  - Amendment Form C for significant changes
- Approved Chemical Safety Form(s) for any carcinogen, toxin, hazardous material, or substance with unknown properties (protocol sections L.3a and b)
- Approved Radioisotopes Form for any new radioisotopes
- Signed DFCI adjuvant policy (policy #P008) if protocol includes research use of adjuvants
- Signed DFCI diphtheria toxin policy (policy #P038) if protocol includes use of diphtheria toxin in live animals

## **Annual Progress Report**

 Annual Progress Report (create New Annual Progress Report and submit online)\*

Important: Any changes to the animal protocol are best submitted by amendment rather than in the Annual Progress Report. See the previous section.

### **3-Year Rewrite**

- Protocol form (create New 3 Year Rewrite and submit online)\*
- New and previously approved Radioisotopes Form (protocol section L.2a; if protocol includes use of radioisotopes)
- New and previously approved Chemical Safety Form(s) for any carcinogen, toxin, hazardous material, or substance with unknown properties (protocol sections L.3a and b)
- Procedural Experience and Contact List (PECL) for all animal users and all animal procedures on protocol
- Signed DFCI adjuvant policy (policy #P008) if protocol includes research use of adjuvants
- Signed DFCI diphtheria toxin policy (policy #P038) if protocol includes use of diphtheria toxin in live animals