3.1 Experiments Requiring IBC Review
Experiments and materials that require IBC review include, but are not limited to:

- **All recombinant or synthetic nucleic acid molecules** experiments NIH classified IIIA-IIIF involving the following:
  - Synthetic nucleic acid molecules that can neither replicate nor generate nucleic acids that can replicate in a living cell;
  - Recombinant or synthetic nucleic acid molecules that are not in organisms;
  - Exact recombinant or synthetic nucleic acid sequence consisting solely from a single source that exists contemporaneously;
  - Recombinant or synthetic nucleic acid molecules from a prokaryotic or eukaryotic host when propagated only in that host;
  - DNA segments from species that naturally exchange DNA;
  - Genomic DNA molecules that have acquired transposable elements;
  - Recombinant or synthetic nucleic acid molecules in tissue culture;
  - *Escherichia coli, Saccharomyces, Kluyveromyces, Bacillus subtilis,* or *Bacillus licheniformis* Host Vector Systems
  - Extrachromosomal elements of gram positive organisms
  - Recombinant or synthetic nucleic acid molecules that are NIH classified III-F
  - The formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus;
  - Influenza viruses generated by recombinant methods or containing genes or sequences from the 1918-1919 H1N1, human H2N2 and highly pathogenic avian influenza H5N1 strains;
  - More than 10 liters of recombinant or synthetic nucleic acid molecules culture in a single vessel;
  - Genetically engineer whole plants and/or organisms associated with plants by recombinant or synthetic nucleic acid molecules methods;
  - Whole animals in which the animal’s genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules or DNA derived into the germ-line (transgenic animal);
  - Viable recombinant or synthetic nucleic acid molecules-modified microorganisms or cell lines tested on whole animals;
  - The use of infectious or defective RG-2 or greater agents;
  - The use of human etiologic and animal viral etiologic agents;
  - DNA from RG 2, RG 3, RG 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems;
  - Risk Group (RG) 2, RG 3, RG 4 or restricted agents as Host-Vector System;
  - The deliberate transfer of recombinant or synthetic nucleic acid molecules or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human research participants (human gene transfer);
  - Deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxic molecules lethal for vertebrates at an LD_{50} of less than 100 ng/kg body weight;
  - The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally;
  - Experiments considered as **Major Actions** under the NIH Guidelines Appendix D.
• **Biohazardous materials, agents or toxins are defined as:**
  o Infectious microorganisms classified as Risk Group 1-4;
  o Human, animal and plant pathogens (bacterial, fungal, parasitic, rickettsial, viral, prions);
  o Research collecting or analyzing human or non-human primate cell lines (established, or primary), tissues, blood, blood products, fluids or other human source material, i.e. sputum, feces, saliva urine. Use of human source material for clinical diagnostic and treatment purposes and/or you receive tissues that have been previously fixed are excluded. (If you will fix tissues, a BUA IS needed);
  o Work with biological toxins (saxitoxin, aflatoxin, venom, etc.);
  o Possession, use and/or transfer of regulated Select Agents and Toxins;
  o Use of animals or derived products from animals that harbor zoonotic agents (e.g. wild trap animals, fecal samples from wild rodents);
  o Use of plants or products of plants that are non-indigenous or noxious weeds.
  o Administration of infectious agents, human or non-human primate tissues, toxic materials, or select agents into animals, animal tissue and/or plants and plant tissues;
  o Large scale cultures of over 10 liters in one vessel
  o Environmental samples collected from areas that may contain infectious agents

* **Recombinant and synthetic nucleic acid molecules are defined as:**
  i. Molecules that are a) constructed by joining nucleic acid molecules and b) that can replicate in a living cell i.e., recombinant nucleic acids;
  ii. Nucleic acid molecules that are chemically or by other means synthesized or amplified including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules i.e., synthetic nucleic acids, or
  iii. Molecules that result from the replication of those described in i. or ii. above.