HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

Committee on Microbiological Safety (COMS) Registration Review Process

COMS meetings are held the last Friday of every month except November and December when the meeting is the third Friday of the month. COMS submittal deadline is three weeks prior to the meeting. If you miss the deadline by one day, it is 7 weeks until the next meeting. Any new registrations or amendments should be submitted to the Biosafety Office, biosafety@harvard.edu no later than the first of the month.

The Harvard Committee on Microbiological Safety (COMS) requires researchers to register all *in vivo* and *in vitro* research involving rDNA, microorganisms, human and non-human primate materials, and creation of transgenic animals. COMS approval is required before IACUC approval will be granted for animal research involving the above mentioned materials. The use of human embryonic stem cells requires additional approval by the Embryonic Stem Cell Research Oversight Committee (ESCRO).

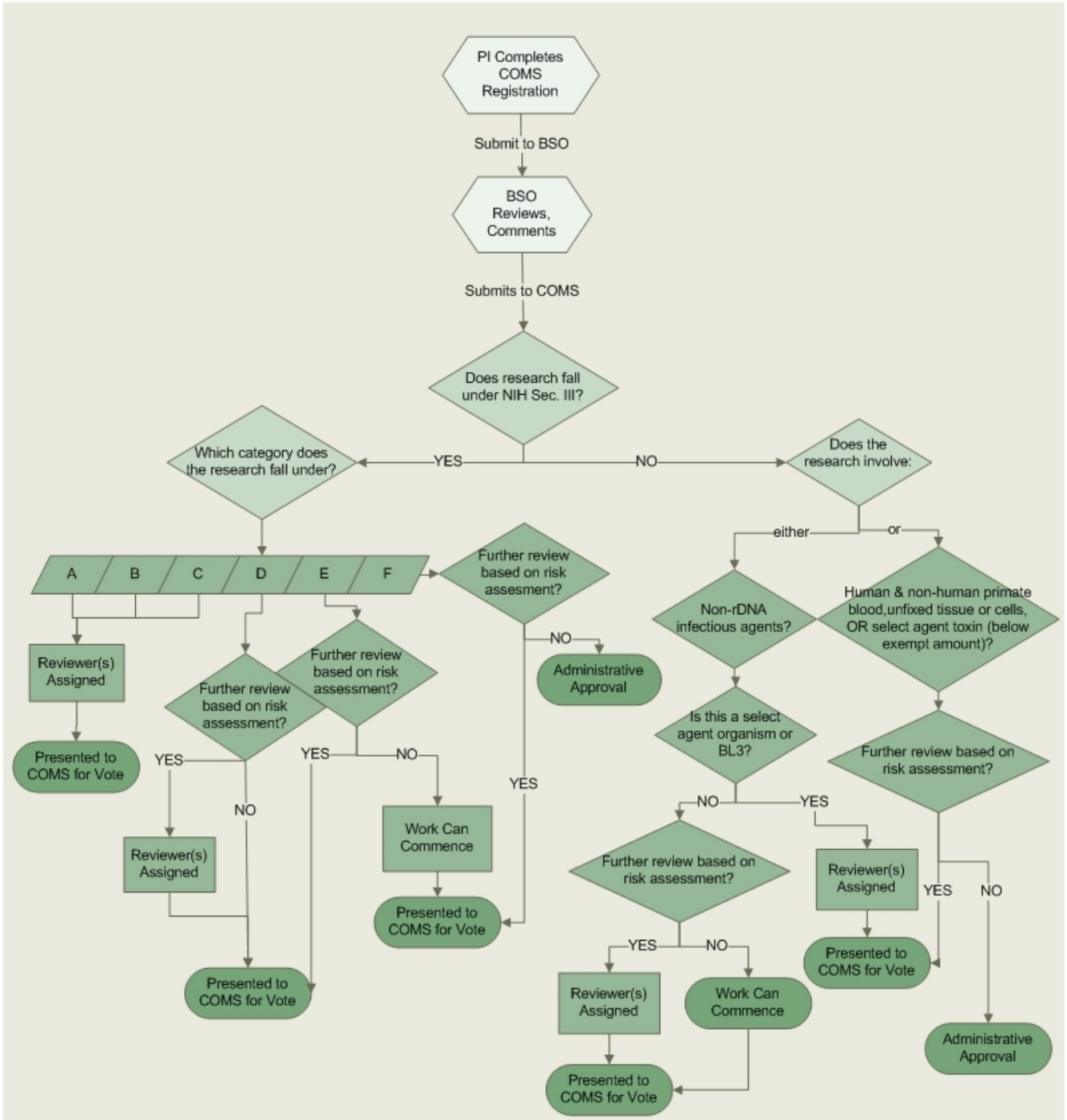
The timeframe for COMS approval and commencement of work depends on the type of experiments being conducted. According to the NIH rDNA Guidelines, some experiments require full committee review before work may begin. The attached flow chart outlines the COMS review process. Below is a general summary of experiments that require full COMS review and those experiments that may commence after expedited review.

Experiments that require full committee review and approval before experiments may begin:

1. rDNA experiments included in section III-D of the NIH rDNA Guidelines, for example:
   - Most *in vivo* experiments with BL2 and BL1 recombinant materials, e.g. viral vectors (lentivirus, vaccinia, adenovirus), transduced cell lines.
   - Creating transgenic animals.
   - Most *in vitro* experiments with BL2 recombinant organisms except recombinant viruses that have <2/3 of the viral genome, e.g. lentivirus and other retroviruses.
   - Most *in vitro* experiments with BL1 viral vectors used with RG2, RG3 or RG4 DNA.
2. Experiments with BL3 pathogens.

Experiments that may begin after expedited review by the Biosafety Officer and Associate Director of COMS:

1. rDNA experiments included in section III-E of the NIH rDNA Guidelines, for example:
   - Most *in vitro* experiments with BL1 viral vectors used with RG1 DNA, e.g. AAV or baculovirus vectors
   - Most *in vitro* experiments with BL2 viral vectors that have < 2/3 of the viral genome, e.g. lentivirus and other retroviruses.
2. *In vivo* or *in vitro* experiments with BL1 or BL2 wild-type microorganisms.
3. Experiments using human and non-human primate blood, tissues, primary cells or cell lines.



Any protocol warranting additional review may be sent for appointed review (i.e. given at least one COMS reviewer prior to general committee review) even if such review is not explicitly indicated on this chart.