

Cloning in *E. coli* (K-12 strains) or use of recombinant K-12 strains

Although exempt from NIH Guidelines (III-F), transforming *E. coli* K-12 strains or culturing recombinant K-12 *E. coli* must be approved by the IBC. IBC applications that include only this work can typically undergo an expedited review. Recombinant protein expression typically uses *E. coli* that is not K-12 and is not exempt from the NIH Guidelines. Use of risk group 3 or 4 genes/sequences, or sequences that produce toxins require a full IBC review.

Follow these steps to add the transformation of E. coli (K-12 strains) or the culturing of recombinant K-12 strains of E. coli to an existing application with multiple IBC oversight activities. These steps can also be used to fill in an application where the transformation or the culturing of E. coli K-12 strains is the only IBC related activity.

- 1) In the “**Activities Include**” section, select “Recombinant or Synthetic Nucleic Acid Molecules.”
- 2) Complete the “**Study Objectives**” section (1) a and b, with a brief description, goals/aims of this exempt work.
- 3) In the “**Recombinant/Synthetic Nucleic Acid Molecules (r/sNA Mol)**” section (2):
 - a) Add a gene transfer method (chemical/physical) and fill in the corresponding pop-out window. Some methods typically used are heat-shock or electroporation of chemically competent *E. coli*. Include the strain of *E. coli* used in the description section (a) of the pop-out window (non-K-12 strains are not exempt). Note that the gene transfer method should be added for the use of recombinant *E. coli* (even when no gene transfer is occurring) or for *E. coli* transformations.
 - b) List, as separate line items, all r/sNA molecules (genes/sequences) under “Genetic Material to be Transferred” (b). (typically *not* the backbone vector genes/sequences unless they will be expressed in eukaryotes)
- 4) In the “**Safety**” section (7) include:
 - a) The laboratory where this work will be performed (a-i).
 - b) Fill in b through h accordingly.
 - c) Under i) Laboratory Procedures, add the experimental activity and appropriate SOP title.
- 5) In the “**Attachments**” section attach:
 - a) Biological Decontamination and Spill Clean-up Plan (tailor to your lab and application)
 - b) Biological Waste Disposal Plan (tailor to your lab and application)
 - c) Attach (no modification required) the SOP “*Biosafety Practices for the Transformation of exempt E. coli K-12 strains and/or Use of Recombinant E. coli K-12 strains*”
see:
<https://research.umn.edu/units/obao/research-oversight-areas/institutional-biosafety-committee-ibc/application-sections-7>



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Office of Biotechnology Activities Oversight/Institutional Biosafety Committee (IBC)