

The Guidelines Explained: Recombinant DNA research

This document was prepared to capture the essence of the NIH guideline requirements and put them into readable form. Many details are omitted, the actual guidelines should be consulted when in doubt. The NIH recombinant DNA guidelines are an intimidating publication. They are long, full of legalese, and have lots of cross references, exceptions, lists, sections, appendices and tables. The NIH rDNA guidelines are legally binding on any institution using NIH funds.

+ me ther h st & carrying rec mbinant DNA. #6, r #64 plus le el c ntainment is rec mmended when(

- o The h st is a n !i us weed
- o The intr duced DNA is the c mplete gen me f an infecti us agent "n wn t n rmally e!ist in the <+,
- o The h st is a plant r micr rganism that may damage ec systems,
- o The h st is a plant with a rec mbinant DNA fr m f reign micr rganisms that are th ught t be safe f r the ec sysytem

'No Wa t n&'

"\$

Exempt Recomb nant DNA @ %ecti n III)/ and Appendi! \$&

: 1 !empt; fr m NIH guidelines means that w r" with these c nstructs need t be submitted t the l#\$ f r n tificati n. The l#\$ will f rward a e!empti n letter f r the rDNA being used in the research. It is <+A p licy f r all registered :e!empt; DNA rec mbinant research t be c nducted at #+6)4.

1 !empt e!periments include(

- A Th se that are n t in rganisms r iruses&
- A Th se that c nsist entirely f DNA segments fr m a single n nchr m s mal r iral DNA s urce, th ugh ne r m re f the segments may be a synthetic equi alent&
- A Th se that c nsist entirely f DNA fr m a pr "ary tic h st including its indigen us plasmids r iruses when pr pagated nly in that h st % r a cl sely related strain f the same species&, r when transferred t an ther h st by well established physi l gical means&
- A Th se that c nsist entirely f DNA fr m an eu"ary tic h st including its chl roplasts, mit ch ndria, r plasmids %but e!cluding iruses& when pr pagated nly in the h st % r a cl sely related strain f the same species&&
- A Th se that c nsist entirely f DNA segments fr m different species that e!change DNA by "n wn physi l gical pr cesses, th ugh ne r m re f the segments may be a synthetic equi alent. +ee Appendices A)I thr ugh A)CI, 1 !empti ns <nder +ecti n III)/)7 @ +ublists f Natural 1 !changers, f r a list f natural e!changers that are e!empt fr m the NIH Ouidelines& r
- A Th se that d n t present a significant ris" t health r the en ir nment % (" ") "*") " + , - &