

HUMAN SUBJECT CODES

Code 10	No Human Subjects Involved
Code 30	Human Subjects Involved, no SRG Comments or Concerns
Code 44	Human Subjects Involved - Certified - SRG Concerns
Code 45	Human Subjects Involved - No Assurance - No SRG
Comments or	Concerns
Code 47	Human Subjects Involved - No Assurance, SRG Comments
Code 49	Human Subjects Involved - No Assurance, SRG Concerns

Inclusion of Women, Minorities, and Children in Clinical Research (Revised codes Effective October 1998)

All biomedical or behavioral research involving human subjects is considered clinical research. Only research projects that meet the NIH definition for Phase III Clinical Trials are coded as Clinical Trials. Only scored applications are assigned codes. All projects/subprojects are individually coded and an overall set of codes assigned to the application. Each project receives Gender, Minority, and Children Codes.

GENDER, MINORITY, AND CHILDREN CODES

An NIH-Defined CLINICAL TRIAL? Y Or N

GENDER CODE:	MINORITY CODE:	CHILDREN CODE:
<i>First character = G</i>	<i>First character = M</i>	<i>First character = C</i>
<i>Second character:</i> 1 = Both Genders	<i>Second character:</i> 1 = Minority & Non-minority	<i>Second character:</i> 1 = Both children & adults
2 = Only Women	2 = Only Minority	2 = Only children
3 = Only Men	3 = Only Non-minority	3 = No children included
4 = Gender Unknown	4 = Minority Representation Unknown	4 = Representation of children unknown
<i>Third character:</i> A = Scientifically Acceptable U = Scientifically Unacceptable	<i>Third character:</i> A = Scientifically Acceptable U = Scientifically Unacceptable	<i>Third character:</i> A = Scientifically Acceptable U = Scientifically Unacceptable