human subjects. OHRP shall provide
guidance to Contracting Officers re-
garding non-award or termination of a
contract due to inadequate assurance
or breach of assurance for protection of
human subjects.

370.302 Types of assurances.
(a) If an institution does not cur-
cently hold an FWA, it should submit
one. An FWA listed in OHRP’s current
“List of Registered Institutional Re-
view Boards (IRBs)/Independent Ethics
Committees (IECs) and Approved As-
surances” is acceptable for the pur-
poses of this policy.

(b) The OHRP Web site includes links
to instructions and the forms for sub-
mitting both a domestic and inter-
national FWA at: http://www.hhs.gov/
ohrp/assurances/assurances_index.html.
To expedite approval of a FWA, as well
as any update/renewal, the institution
shall use the OHRP Electronic Submis-
sion System. Once the institution
“submits” an electronic file to OHRP,
the institution must fax or mail (but
not both) a copy of the signature page
to initiate the review process. The in-
stitution shall mail the FWA to the
OHRP, U.S. Department of Health and
Human Services, 1101 Wootton Park-
way, Suite 200, Rockville, Maryland
20852, or fax it to OHRP at 240–453–8202
(but not both).

370.303 Notice to offerors.
(a) The Contracting Officer shall in-
sert the provision in 352.270–4(a), Notice
to Offerors of Requirements of 45 CFR
Part 46, Protection of Human Subjects,
in solicitations that involve human
subjects.

(b) Institutions having an OHRP-ap-
proved FWA shall certify IRB approval
of submitted proposals in the manner
required by instructions for completion
of the contract proposal; by completion
of an OMB Form No. 0990–0263, “Pro-
tection of Human Subjects Assurance
Identification/IRB Certification/Decl-
arion of Exemption (Common Rule);”
or by letter indicating the institution’s
OHRP-assigned FWA number, the date
of IRB review and approval, and the
type of review (convened or expedited).
The date of IRB approval must not be
more than 12 months prior to the dead-
line for proposal submission.

(c) The Contracting Officer generally
will not request FWAs for contractors,
subcontractors, or cooperating institu-
tions prior to determination that a
contract proposal has been selected for
negotiation. When a contractor sub-
mits an FWA, it provides certification
for the initial contract period. No addi-
tional documentation is required. If
the contract provides for additional
years to complete the project, the con-
tactor shall certify the noncompeti-
tive renewal proposal in the manner
described in the preceding paragraph.

370.304 Contract clauses.
(a) The Contracting Officer shall in-
sert the clause in 352.270–4(b), Protec-
tion of Human Subjects, in solicita-
tions, contracts, and orders that in-
volve human subjects.

(b) The Contracting Officer shall in-
sert the clause in 352.270–6, Restriction
on Use of Human Subjects, in contracts
and orders if the contractor has an ap-
proved Federal-wide assurance of com-
pliance in place, but cannot certify
prior to award that the research has
been reviewed and approved by the IRB
designated under the contractor’s Fed-
eral-wide assurance of compliance, be-
cause definite plans for involvement of
human subjects are not set forth in the
proposal (e.g., projects in which human
subjects’ involvement will depend upon
completion of instruments, prior ani-
mal studies, or purification of com-
pounds). Under these conditions, the
Contracting Officer may make the
award without the requisite certifi-
cation, as long as the Contracting Offi-
cer includes appropriate conditions in
the contract or order.

Subpart 370.4—Acquisitions In-
volving the Use of Laboratory
Animals

370.400 Scope of subpart.
This subpart applies to all R & D, re-
search training, biological testing,
housing and maintenance, and other
activities involving live vertebrate ani-
mal conducted under contract (see