U-MIC TRANSCRIPT
Flexibility Initiatives: Exemption 7 and Two-Year Approval

To utilize federal regulations' existing flexibility regarding non-federally-funded, non-FDA regulated research, IRBMED has launched two new initiatives: Exemption 7 and two-year approval periods. Exercise of these initiatives falls wholly within the IRB's discretion; before proceeding, IRB staff will ask the researcher to verify that the study satisfies all appropriate criteria.

IRBMED may now choose to grant Exemption category 7 to certain studies in which research activity is limited to analysis of a *single dataset containing identifiable information*. This exemption eliminates the need for researchers to submit annual scheduled continuing reviews when the only study activity is data analysis.

To ensure that a study qualifies for Exemption 7, IRB staff will ask the researcher to verify that the study

- poses *no more than minimal risk* to subjects
- undertakes no activity other than analysis of a single data set containing identifiable data
- and includes *none* of the following:
    - federal funding or federal training grants
    - FDA-regulated components
    - sponsor or other contractual restrictions
    - clinical research interventions, including behavioral interventions
    - previous restrictions on data use (such as data use agreements or previous informed consent restrictions)
    - or receipt of an NIH issued Certificate of Confidentiality

Studies intended to support future proposals for federal funding should not be granted exemption 7. Initial applications are not eligible for Exemption 7.

As its second new flexibility initiative, IRBMED may now opt to issue *two-year* approval for certain studies whose subject protections comply with federal regulations. The longer approval period eliminates the need for researchers to submit annual scheduled continuing reviews (or SCRs).

All other regulatory requirements—including those pertaining to amendments and adverse event and ORIO reporting—remain unchanged.

To ensure that a study qualifies for two-year approval, IRB staff will ask the researcher to verify that the study

- poses no more than minimal risk to subjects
- and includes *none* of the following:
    - federal funding or federal training grants

- FDA-regulated components
- sponsor or other contractual restrictions
- clinical research interventions (including behavioral interventions)
- prisoners as subjects
- or receipt of an NIH issued Certificate of Confidentiality

Unlike with Exemption 7, IRBMED may choose to issue two-year approval periods for initial applications.

Examples of research that IRBMED may choose to grant two-year approval include

- secondary use of identifiable data or specimens (both prospective and retrospective), not otherwise exempt from IRB oversight
- or survey, focus group, or interview projects not otherwise exempt from IRB oversight

IRBMED may, in its discretion, choose not to issue an Exempt 7 determination or two-year approval, even though a study meets the criteria.

Contact IRBMED for more information about Exemption 7 and two-year approval periods.

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