



STATEMENT OF PRACTICE

Flexibility Initiative: Exemption 7

Effective: May 1, 2015

Note: IRB applications granted Exemption 7 may **not** be used to support proposals or future awards involving federal funding.

Note: Exemption 7 may **not** be used for new applications.

I. STATEMENT OF PRACTICE

To exercise existing flexibility in the application of federal regulations to non-federally funded, non-FDA regulated studies, IRBMED will begin granting a new exempt determination (Exemption 7) to studies in which research activity is limited to analysis of a *single dataset containing identifiable information*. This exemption would eliminate the need for principal investigators to submit yearly scheduled continuing reviews where the only study activity is data analysis.

II. PROCESS

Studies transitioning (at SCR or during AME) from an existing regulated application must meet the eligibility criteria cited below. (Initial applications are **not** eligible for Exemption 7)

To qualify for Exemption 7, studies must:

- Pose *no more than minimal risk* to subjects,
- Undertake no activity other than analysis of a single data set containing identifiable data

AND

- Must *not* include any of the following:
 - Federal funding or federal training grants (direct or prime sponsorship)
 - FDA regulated components
 - Sponsor or other contractual restrictions
 - Clinical research interventions (including behavioral interventions)
 - Previous restrictions on data use (e.g., data use agreements, previous informed consent restrictions)
 - Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data

All other regulatory requirements pertaining to exemptions remain unchanged. IRBMED retains the right to not issue the Exempt 7 determination in certain circumstances.

III. RESOURCES

- U-M HRPP Policy Innovation & Demonstration Initiative <http://research-compliance.umich.edu/hrpp-innovation-demonstration-initiative>
- [FDA Guidance 2012](#), IRB Continuing Review after Clinical Investigation Approval
- [OHRP Guidance 2010](#), Guidance on IRB Continuing Review of Research
- U-M Exemption categories: <http://research-compliance.umich.edu/operations-manual-activities-subject-hrpp#UMcategories>