Human Subjects Research
Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated.

Examples of human subjects research include:

- Collecting blood
- Conducting a survey
- Changing participants’ environment
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique

Included in the NIH application:

- Protection of Human Subjects attachment

If funded, grantees will need:

- An Institutional Federal-Wide Assurance (FWA) with OHRP
- IRB approval or determination of exemption
- Human Subjects education* even for exemptions

If research meets the criteria for one of the eight categories of activities that are **exempt** from the federal regulations, not all of the above may apply. Some of the exemptions require a limited IRB review (7 and 8, and some designs under 2 and 3).

Exemptions:

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<tr>
<th>Exemption 1</th>
<th>Exemption 2</th>
<th>Exemption 3</th>
<th>Exemption 4</th>
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<tbody>
<tr>
<td>Conducted in an educational setting involving normal education practices</td>
<td>Use of educational tests, surveys, interviews, or observations of public behavior</td>
<td>Use of benign behavioral interventions in adults</td>
<td>Collection/study of data or specimens if publicly available or recorded such that subjects cannot be identified*</td>
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*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

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<thead>
<tr>
<th>Exemption 5</th>
<th>Exemption 6</th>
<th>Exemption 7</th>
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<td>Public service program research or demonstration projects</td>
<td>Taste and food quality evaluations</td>
<td>Storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.</td>
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Questions/comments? Contact OER-HS@nih.gov