# Flex Model Cheat Sheet – Dec 2019

## Not Allowed

1. Federally funding research  
2. WV CTSI, WV-INBRE, CoBRE supported research (in whole or part) or other federally funded research  
3. Research with FDA regulated elements  
   a) Research which would otherwise be approvable under Expedited Category 1 (45 CFR 46.110) (i.e., drugs and devices used according to approved labeling).  
   b) Research requiring an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application(s).  
4. Research involving sensitive topics  
   a) Suicide/suicide ideation  
   b) Traumatic life events that may evoke powerful emotion or induce mood changes in participants  
   c) Identifiable results of drug misuse/abuse, criminal history, and/or other behaviors which may put the participant at risk  
5. Studies with Certificate of Confidentiality  
6. International research sites  
7. Populations targeted as part of the study  
   - Prisoners  
   - Tribal members  
   - Military personnel  
   - Wards of the state  
   - Cognitively impaired

## Allowed

1. Non-federally funded research  
2. No more than minimal risk  
3. Research involving tissues and samples collected under standard of care procedures  
   a) Research that would otherwise be permitted and approved under Expedited Categories 2 and 3 (45 CFR 46.110) are eligible for review using the Flex Application.  
4. Review of data that have been collected, or will be collected, solely for non-research purposes  
   a) Research that would otherwise be permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110) is eligible for review using the Flex Application.  
5. Research that would otherwise be permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110) is eligible for review using the Flex Application.

## Other Topics & Concerns

<table>
<thead>
<tr>
<th>Topic</th>
<th>Allowed?</th>
<th>Conditions...</th>
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<tbody>
<tr>
<td>Pregnant Women</td>
<td>YES, if...</td>
<td>Consent must be obtained using Flex Consent Form</td>
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| Children (under 18)| YES, if...| Consent & Assent must be obtained using Flex Consent Form  
   - A waiver is permissible if justified |
| Deception           | YES, if...| Debriefing plan is in place and subjects were given the option to opt-out. |
| Genetic Testing     | NO       |                                                   |
| IAA Required        | NO       |                                                   |

Flex Model information can be found on the IRB Forms and IRB Guidance pages.

V2: 12/30/2019