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| The purpose of this worksheet is to provide IRB members with additional considerations that may become relevant when reviewing Human Research during an emergency/disaster situation. These additional considerations may provide additional and necessary flexibility for study teams while continuing to assure research subject safety during the emergency/disaster. This worksheet is to be used when directed to do so by the IRB Chair or staff. It does not need to be completed or filed. | |
| 1. **More widespread use of waivers of documentation of consent for minimal risk research**: Additional use of waivers of documentation of consent may be appropriate if the following items are true. (Check if “Yes.” All must be checked) | |
|  | The research involves no more than Minimal Risk to the subjects. |
|  | The research involves only interaction, not intervention, with subjects. |
|  | The emergency/disaster may create additional challenges in notifying participants of changes to consent documents. |
|  | The research meets one of the eligibility categories for waiver of written documentation of consent listed in HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent |
| 1. **Alternate mechanisms for safety monitoring.** (Check if “Yes.” All must be checked) | |
|  | The research involves protocol-specified visits to the investigational site. |
|  | Research subjects may not be able to come to the investigational site for protocol-specified visits due to the emergency/disaster. |
|  | Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) are available. |
|  | Alternative methods for safety assessments can feasibly be implemented. |
|  | Alternative methods for safety assessments) would be sufficient to assure the safety of trial participants. |
| 1. **Additional flexibility in oversight of research not subject to federal regulations.** (Check if “Yes.” All must be checked) | |
|  | The research is not covered by federal regulations. |
|  | One or more of the following options is feasible and appropriate during an emergency/disaster to provide necessary flexibility for study teams while continuing to assure research subject safety:  Extend continuing review dates during the anticipated period an emergency.  Allow minor changes to be reported to the IRB or EC without requiring IRB or EC approval prior to implementation. |
| 1. **Other mechanisms for additional flexibility not described above**. In addition to the options above, additional considerations in providing added flexibility to study teams during emergency/disaster situations may be appropriate where any of the following is true. (Check if “Yes”) | |
|  | Additional institution-level information related to emergency/disaster planning (and not otherwise specified above) provides additional guidance in providing additional flexibility or support to study teams managing research during and emergency/disaster. |
|  | Federal guidance or communications related to managing research during the emergency/disaster is issued and provides additional flexibility or resources. |
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