**Worksheet 313 – Eligibility Criteria for Expedited Review**

File Number:  IRB Reviewer: Date of Review:

P.I. Name:

Study Title or Short Title:

**Type of Application (check one):**

Initial Review

Continuing Review

Modification

Study Closure (may be administratively processed)

|  |  |  |
| --- | --- | --- |
| **Check all that apply** | **Category** | **Description** |
|  | 1 | Clinical studies of drugs and medical devices when an IND or IDE application is not required by the FDA. |
|  | 2a | Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds. |
|  | 2b | Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from other adults and children, considering the age, weight and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. |
|  | 3 | Prospective collection of biological specimens for research purposes by non-invasive means. |
|  | 4 | Collection of data through non-invasive procedures, not involving general anesthesia or sedation, routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. |
|  | 5 | Research involving materials, such as data, documents, records, or specimens, that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis. |
|  | 6 | Collection of data from voice, video, digital, or image recordings made for research purposes. |
|  | 7a | Research on individual or group characteristics or behavior, including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior. |
|  | 7b | Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance. |
|  | 8a | Continuing Review if the study is permanently closed to enrollment of new participants:   1. All subjects have completed all research-related interventions, and 2. The research remains active only for long-term follow-up of subjects |
|  | 8b | Continuing Review where no participants have been enrolled at the UH site since the study received initial IRB approval and no additional risks have been identified at any site |
|  | 8c | Continuing Review if the remaining research activities are limited to data analysis. |
|  | 9 | Continuing Review if:   1. The study is not conducted under an IND or IDE application, and 2. Categories 2 – 8 do not apply, but 3. The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. |
|  | 110b | Minor modification that must not materially:   1. Alter the assessment of risks and potential benefits of the study; 2. Increase the level of risk to the physical, emotional, or psychological well-being of participants, including loss of confidentiality; or 3. Change |