Human Subjects Research Determination.
To be completed by qualified staff member.

Review the following questions to determine if the activity constitutes human subjects research.

- **Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?**
  - **38 CFR 16.102(l)** Generalizable knowledge consists of theories, principles, or relationships (or the accumulation of data on which they may be based) that can be corroborated by accepted scientific observation and inference that is applicable to other related situations, populations, or devices outside of the tested situation.
  - **No** → Activity is not research*
    - **Activity is not research**
      - **Comment:**
  - **Yes** → Activity is research.
    - **Does the research involve obtaining information about living individuals?**
      - **32 CFR 219.102(f)**
        - **No** → Activity is Research Not Involving Human Subjects.**
          - **Comment:**
        - **Yes** → Activity is human subject research and 38 CFR 16 applies.
          - **Is the information individually identifiable?**
            - **No**
              - **Is the information private?**
                - **No**
                  - Activity is Human Subject Research – Seek Further Determination
                - **Yes**
                  - **Comment:**
          - **Yes**
            - **Comment:**

This activity has been determined to be (check one):

- **Not Research – submit to Department Chief or Quality management**
  - **Comment:**
- **Research Not Involving Human Subjects - Report to R&DC**
  - **Comment:**
- Human Subject Research – Seek Further Determination

Reviewer Name (Print): ______________________
Reviewer Name (Sign): ______________________  Date: ______________