TITLE: **IRB Meeting Minutes**

PURPOSE: Outline process for recording minutes for convened IRB meetings

RESPONSIBILTIES: HSPP Staff

PROCEDURES:

- Minutes are to comply with regulatory and guidance requirements.
- Minutes are to record separate deliberations for each action.
- Minutes can be officially approved on behalf of the IRB by the IRB chair.
- IRB members may make corrections to minutes.
- The HSPP staff writes makes minutes and them available for review within three weeks of the meeting date.
- Minutes may not be altered by anyone including a higher authority once approved by the Chair.

Use UAR to record the following information for convened IRB meetings:

- Name of each voting member (regular and alternates) present at the meeting at any time (do not record non-voting members).
- If applicable, name of each voting member present via teleconference. Indicate whether members received all pertinent materials before the meeting and were able to actively and equally participate in all discussions.
- Number of members required for quorum:
    - Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the roster, 11/2=5.5 and the next whole number is 6.
- Meeting start time.
- Summary of each business item discussed.
- For each protocol reviewed:
    - Investigator name
    - IRB project number
    - Protocol title
    - Type of review:
        - Initial review
        - Renewal
        - Review of amendment to previously approved research
    - Description of review (a brief, bulleted description of the changes being proposed)
    - Consultant report (summarize the key information provided by the consultant), if applicable.
    - General discussion (summary of the discussion held between IRB members, HSPP staff, consultants and other guests)

- Controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution. Indicate controverted issues by adding [*Controverted issue*] in the discussion text. If there was no resolution, document this.
- Motion.
  - Approved
  - Approved with conditions
  - Deferred
- Disapproved Level of risk: Minimal risk or greater than minimal risk.
- Identify regulatory determinations and reference the protocol-specific findings supporting these determinations as requested by the Principal Investigator.
- Period of approval: Indicate the length of time that the IRB determined was appropriate for re-review of the item. NOTE: An amendment may change the period of approval if the risk:benefit ratio is such that the IRB determines a greater or less frequent period of review is necessary.
- As applicable, include:
  - Justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS- approved sample consent document;
  - Rationale for a significant/non-significant device determination;
  - Changes required to secure approval;
  - Reasons the IRB tabled the protocol; and
  - Reasons for the deferral or disapproval and recommended changes.
- Vote.
  - Record as the number of members for, against, abstaining, absent or recused
    - For: voting for the motion
    - Against: voting against the motion
    - Abstain: Present for the vote, but not voting "For" or "Against"
    - Absent: Listed under "Members Present" but not present for the discussion and vote on this particular protocol for reasons other than Conflicting Interest. List the names of absent member sin the vote (For example: For: 7; Against: 3; Abstain: 2; Absent: 2 (Alice Baker, Charlie Delta); Recused: 0).
    - Recused: Listed under "Members Present" but not present for the discussion and vote on the particular protocol because of a Conflicting Interest. List the names of recused members in the vote (For example: For: 7; Against: 3; Abstain: 2; Absent: 0; Recused: 2 (Evelyn Foxtrot, George India)

- For each Reportable Item reviewed record:
  - Description of problem.
  - General Discussion (Summary of the key discussion held between IRB member, HSPP staff, consultants, and other guests
  - Controverted issues and their resolution
  - Motion. Include any IRB determination of whether the problem is

        - An unfounded Allegation of Non-Compliance,
        - Non-Compliance that is neither Serious nor Continuing Non-Compliance,
        - Serious or Continuing Non-Compliance,
        - Not an Unanticipated Problem Involving Risks to Subjects or Others,
        - An Unanticipated Problem Involving Risks to Subjects or Others.
    - Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused.
    - Reasons for Suspension or Termination of IRB Approval.
- Record the meeting end time.

Revise the minutes for accuracy and send for review and approval by the attending IRB Chair.

Attach the following documents to the minutes:

- List of protocols granted approval as exempt.
- List of protocols granted approval using the expedited procedure.
- List research approved with changes to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.
- List of amendments to approved Human Research approved using the expedited procedure.
- List of protocols granted re-approval using the expedited procedure.

Store the approved minutes and associated approval email from the Chair in the HSPP records.

Follow SOP-070: IRB Records.

MATERIALS:

- SOP-070: IRB Records
- T501 - Minutes

REFERENCES:

- 45 CFR §46.115(a)(2)
- 21 CFR §56.115(a)(2)

REVIEW/REVISIONS: From 10/10/2010 version: Updated to match T501: IRB Minutes template, adding general discussion and description of review.
Form 08/01/2011 version: Referenced Operations Manual; Updated procedures to be consistent with current practice; Updated naming convention to match UAccess Research (UAR); Removed reference to VA.

From 01/2014 version: Renumbered from P&P-043; References to P&P-070 revised to SOP-070 to reflect new numbering system.