1. PURPOSE
   1. This procedure establishes the process to conduct annual evaluations of the human research protection program.
   2. The process begins the first business day of each June.
   3. The process ends when all evaluations have been completed and communicated to those evaluated.
2. REVISIONS FROM PREVIOUS VERSION

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| Version | Date | Revisions |
| R00 | 3/25/14 | Original issue |
| R01 | 9/8/17 | Discuss deficiencies, remove copy of evaluation provided to members, remove letter of appreciation, remove evaluation of subject outreach plan |
| R02 | 12/12/19 | Logo, add document number in footer, remove ref. to evaluation of subject outreach plan, remove copy to IO or designee for IRB chair, add if requested for copies to IO, change IRB and FWA requirements for updating, remove brochure and template letter in materials |
| R02 | 12/16/2020 | Annual review, no changes |
| R02 | 10/8/21 | Annual review, no changes |
| R03 | 12/27/22 | Annual review, added evaluation of CTSI community involvement |
| R03 | 11/14/23 | Annual review, no changes |

1. POLICY
   1. The human research protection program is evaluated annually.
2. RESPONSIBILITIES
   1. IRB staff ensure completion of these procedures.
3. PROCEDURE
   1. Have the Organizational Official or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.
      1. Space
      2. HRPP educational program
      3. Legal counsel
      4. Conflicts of interests
      5. Quality improvement plan
   2. Evaluate whether the number of IRB meetings is appropriate to the volume and types of research reviewed.
      1. Notify the Organizational Official or designee of any deficiencies.
      2. If the number of IRB meetings is not appropriate to the volume and types of research reviewed, work with the Organizational Official or designee to modify the IRB structure.
   3. Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
      1. Notify the Organizational Official or designee of any deficiencies.
      2. If needed, work with each IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.
   4. Have the Organizational Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
      1. Provide each IRB chair with a copy of his or her evaluation.
      2. If needed, work with each IRB chair to develop a plan to improve the individual’s knowledge, skills, and performance.
   5. Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
      1. Provide a copy of the evaluation to the Organizational Official or designee, if requested.
      2. Provide each IRB staff with a copy of his or her evaluation.
      3. If needed, work with each IRB staff person to develop a plan to improve the individual’s knowledge, skills, and performance.
   6. Evaluate the CTSI Community Involvement Program through consideration of the following factors.
      1. Whether the program initiatives increase the enrollment of underrepresented groups to reflect the demographics of the Buffalo area.
      2. Whether the CTSI resources are being regularly utilized by the IRB or research community.
      3. Provide a copy of the evaluation to the Organizational Official or designee, if requested.
   7. Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
      1. Provide a copy of the evaluation to the Organizational Official or designee, if requested.
      2. If the composition of an IRB does not meet regulatory and organizational requirements, work with the Organizational Official or designee to modify the IRB composition.
   8. Check when the last time each IRB was registered. If updates are required, update the registration.[[1]](#footnote-1)
   9. Check when the last time the federalwide assurance (FWA) was updated or renewed. If it will expire prior to the next review or if changes are necessary, update/renew the federalwide assurance (FWA).[[2]](#footnote-2)
4. MATERIALS
   1. WORKSHEET: IRB Composition (HRP-304)
5. REFERENCES
   1. None

1. See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#footnote-ref-1)
2. See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#footnote-ref-2)