

## **REVISIONS** - Indiana State University Policies and Procedures for the Review of Research Involving Human Subjects

02/17/11 Revised - **Section A**

### **A.3 has been changed from:**

PIs should submit their application packet directly to the IRB administrator, care of OSP, for review by the IRB. A new application consists of Form A, including answers to all research description questions; Form B (exempt research checklist) or Form C (expedited review research categories), if applicable; and the research grant proposal, if the PI is seeking funding or has received funding. Similarly, any submissions after IRB approval, including modification requests (Form D), continuation requests (Form E), adverse event written reports (Form F) and completion of research activities (Form G) should be submitted to the IRB administrator, care of OSP. Refer to Appendix 1 for more information on submission materials and for copies of the forms. The IRB administrator will forward the materials to the IRB chairperson, vice chairperson, or designated IRB member who will determine the level of review required. The IRB chairperson, vice chairperson, or designated IRB member will correspond directly with the PI regarding the submission. Correspondence of the PI regarding revisions to the submission materials or questions may be directed to the IRB chairperson, vice chairperson, or designated IRB member and may be conducted through e-mail.

Reports of adverse events must be reported immediately via phone or e-mail to the IRB chairperson or vice chairperson. A written report of the adverse event, using Form F, must then be submitted to the IRB administrator, care of the OSP, within 5 working days after first awareness of the problem. Refer to Section G for more information.

### **To the following to update for IRBNet:**

PIs should submit all new applications, modification requests, continuation requests, completion of research activities report, and reports of problems involving risk, adverse effects, and non-compliance via IRBNet. Refer to Appendix 1 for more information on submission materials and for copies of the forms. IRBNet will send a notification to the IRB chairperson, vice chairperson, and the administrator when the PI submits materials within IRBNet. The IRB chairperson, vice chairperson, or designated IRB member will review the application for completion, and, once the application has been deemed complete, determine the level of review required. The IRB chairperson, vice chairperson, or designated IRB member will correspond directly with the PI within IRBNet regarding the submission. Correspondence of the PI regarding revisions to the submission materials or questions must be conducted through IRBNet.

Reports of adverse events must be reported immediately via phone or e-mail to the IRB chairperson or vice chairperson. A written report of the adverse event, using Form F, must then be submitted to the IRB via IRBNet within 5 working days after first awareness of the problem. Refer to Section G for more information.

02/17/11

Revised - **Section B**

**B.2, 1<sup>st</sup> paragraph, has been changed from:**

The following actions are the responsibility of the chairperson of the IRB. He or she shall have the administrative and clerical assistance of the IRB administrator or an individual designated by the IRB administrator in carrying out these duties:

**To the following as a change in procedures:**

The following actions are the responsibility of the chairperson of the IRB. He or she shall have the administrative assistance of the IRB administrator or an individual designated by the IRB administrator in carrying out these duties:

**B.2, 4th bullet, has been changed from:**

- Send each PI a letter informing him or her of the IRB's decision and actions after initial, continuation, modification, adverse event review, or upon any other action taken by the IRB.

**To the following to update for IRBNet:**

- Post a letter within IRBNet informing each PI of the IRB's decision and actions after initial, continuation, modification, adverse event review, or upon any other action taken by the IRB.

**B.3, 1<sup>st</sup> paragraph, sentence 4, has been changed from:**

When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project, however, the IRB may ask them to provide information about the project or they make excuse themselves from the meeting during the review.

**To the following to correct a typographical error:**

When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project, however, the IRB may ask them to provide information about the project or they may excuse themselves from the meeting during the review.

02/17/11

Revised - **Section D**

**1st bullet has been changed from:**

- Retain ISU's federalwise assurance, copies of pertinent federal regulations, policies and guidelines related to the involvement of human subjects, as well as ISU's policies and procedures;

**To the following to correct a typographical error:**

- Retain ISU's Federalwide Assurance, copies of pertinent federal regulations, policies and guidelines related to the involvement of human subjects, as well as ISU's policies and procedures;

**The following bullets have been deleted to update for IRBNet:**

- Prepare and distribute meeting packets and agendas;
- Maintain records of IRB proceedings and decisions;
- Receive submissions from PIs and forward the submissions to the IRB chairperson, vice chairperson, or designated IRB member;
- Maintain a filing system of submissions to the IRB;
- Maintain a log containing new applications, modification requests, adverse event reports, continuation requests, and completion reports;
- Send each PI Form E, as a reminder that a continuing request is needed, no less than 6 weeks before the expiration of IRB approval of the protocol;

02/17/11

Revised - **Section E**

**E.1, 3<sup>rd</sup> bullet (as follows) has been deleted to reflect a change in procedure:**

- When a full review is required, attend the IRB meeting at which the application is reviewed, in accordance with Section F of ISU policy.

**E.1, 4<sup>th</sup> bullet (previously 5<sup>th</sup> bullet), last sentence, has been changed from:**

If the project involves new drugs or devices, FDA requirements must be satisfied.

**To state the following to reflect a procedural change:**

If the project involves new drugs or devices, FDA requirements must be satisfied (refer to Section R).

**E.1, 5<sup>th</sup> bullet (previously 6<sup>th</sup> bullet), has been changed from:**

- If changes are needed in an approved protocol, submit the proper application to modify the protocol and wait to receive written approval before implementing any changes.

**To state the following to update for IRBNet:**

- If changes are needed in an approved protocol, submit the proper documentation via IRBNet to modify the protocol and wait to receive written approval before implementing any changes.

**E.1, 10th bullet (previously 11<sup>th</sup> bullet), has been changed from:**

- Keep certification for all investigators current regarding training to conduct research with human subjects, as required in Section N of ISU's policy.

**To the following to correct a typographical error:**

- Keep certification for all investigators current regarding training to conduct research with human subjects, as required in Section O of ISU's policy.

**E.2, 3rd bullet, has been changed from:**

- All decisions of the IRB shall be conveyed to the PI in writing.

**To state the following to update for IRBNet:**

- All decisions of the IRB shall be conveyed to the PI in writing via IRBNet.

**E.3, 4<sup>th</sup> sentence, has been changed from:**

If the research project will continue at ISU under another investigator, the PI must submit Form D, and the IRB will follow the review guidelines set forth in this policy.

**To state the following to update for IRBNet:**

If the research project will continue at ISU under another investigator, the PI must submit Form D via IRBNet, and the IRB will follow the review guidelines set forth in this policy.

02/17/11

Revised - **Section F**

**F.1.1.1, 1<sup>st</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI may request that the research application receive exemption certification by submitting Form B with his or her application.

**To state the following to update for IRBNet:**

The PI may request that the research application receive exemption certification by submitting Form B with his or her application within IRBNet.

**F.1.1.1, 1<sup>st</sup> paragraph, 7<sup>th</sup> sentence, has been changed from:**

The PI may expect written notification of the status of the project (i.e., certified, additional information or modifications needed, or denial of exemption certification) within 10 working days of receipt of the research application by the IRB administrator (care of OSP).

**To state the following to update for IRBNet:**

The PI may expect written notification of the status of the project (i.e., certified, additional information or modifications needed, or denial of exemption certification) within 10 working days of receipt of the completed research application within IRBNet.

**F.1.1.1, 2<sup>nd</sup> paragraph, 1<sup>st</sup> bullet, 1<sup>st</sup> sentence, has been changed from:**

The PI is sent an exemption certification letter.

**To state the following to update for IRBNet:**

An exemption certification letter will be posted in IRBNet.

**F.1.1.1, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> bullet, 2<sup>nd</sup> and 3<sup>rd</sup> sentences, has been changed from:**

The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). If the IRB chairperson, IRB vice chairperson, or designated IRB member is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption certification letter is sent to the PI.

**To state the following to update for IRBNet:**

The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI via IRBNet to request the required additional information or modification(s). If the IRB chairperson, IRB vice chairperson, or designated IRB member is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption certification letter is posted in IRBNet.

**F.1.2.1, 1<sup>st</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI may request that the research application receive expedited review by submitting Form C with his or her application.

**To state the following to update for IRBNet:**

The PI may request that the research application receive expedited review by submitting Form C with his or her application within IRBNet.

**F.1.2.1, 1<sup>st</sup> paragraph, 7th sentence, has been changed from:**

The PI should expect notification that revisions are required prior to the second review, the application has been sent to a second reviewer, or the application needs full review within 10 working days of receipt of the new application by the IRB.

**To state the following to update for IRBNet:**

The PI should expect notification that revisions are required prior to the second review, the application has been sent to a second reviewer, or the application needs full review within 10 working days of receipt of the new application in IRBNet.

**F.1.2.1, 2<sup>nd</sup> paragraph, 1<sup>st</sup> bullet, 2<sup>nd</sup> sentence, has been changed from:**

The PI is sent a letter of approval and the informed consent or assent form with the IRB approval validation stamp. (See Section J.1 for more information about the validation stamp.)

**To state the following to update for IRBNet:**

A letter of approval and the informed consent or assent form with the IRB approval information is posted in IRBNet. (See Section J.1 for more information about the validation information.)

**F.1.2.1, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> bullet, has been changed from:**

Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or a designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is sent to the PI.

**To state the following to update for IRBNet:**

Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or a designated IRB member will contact the PI via IRBNet to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is posted in IRBNet.

**F.1.2.1, 2<sup>nd</sup> paragraph, 3<sup>rd</sup> bullet, 3<sup>rd</sup> sentence, has been changed from:**

The PI will be notified in writing that a full review is required and will be informed of the reasons for this decision.

**To state the following to update for IRBNet:**

The PI will be notified via IRBNet that a full review is required and will be informed of the reasons for this decision.

**F.1.2.2, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI will submit Form D for review.

**To state the following to update for IRBNet:**

The PI will submit Form D for review via IRBNet.

**F.1.2.2, 2<sup>nd</sup> paragraph, 1<sup>st</sup> bullet, has been changed from:**

Approve the requested modifications. The PI is sent a letter of approval of the requested modifications.

**To state the following to update for IRBNet:**

Approve the requested modifications. A letter of approval of the requested modifications will be posted in IRBNet.

**F.1.2.2, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> bullet, has been changed from:**

Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the requested modifications meet the IRB review criteria, the modifications are approved and a letter of approval is sent to the PI.

**To state the following to update for IRBNet:**

Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI via IRBNet to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the requested modifications meet the IRB review criteria, the modifications are approved and a letter of approval is posted in IRBNet.

**F.1.2.2, 2<sup>nd</sup> paragraph, 3<sup>rd</sup> bullet, 3<sup>rd</sup> sentence, has been changed from:**

The PI will be notified in writing that a full review by the IRB is required and will be informed of the reasons for this decision.

**To state the following to update for IRBNet:**

The PI will be notified via IRBNet that a full review by the IRB is required and will be informed of the reasons for this decision.

**F.1.2.3, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> and 3<sup>rd</sup> sentence, has been changed from:**

The PI will submit Form E. The IRB chairperson, IRB vice chairperson, or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via e-mail if a full review is needed.

**To state the following to update for IRBNet:**

The PI will submit Form E via IRBNet. The IRB chairperson, IRB vice chairperson, or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI via IRBNet if a full review is needed.

**F.1.2.3, 3<sup>rd</sup> paragraph, 3<sup>rd</sup> sentence, has been changed from:**

A notification letter will be sent by the IRB chairperson or vice chairperson to the PI and, if appropriate, the funding agency.

**To state the following to update for IRBNet:**

A notification will be sent by the IRB chairperson or vice chairperson to the PI via IRBNet and, if appropriate, the letter will be sent to the funding agency.

**F.1.2.4 has been changed from:**

For a completed research project that has undergone expedited review, the PI must submit Form G on or before the IRB approval expiration date. This will allow the IRB to close the active file. The IRB administrator will send Form G at least 6 weeks prior to expiration of IRB approval.

**To state the following to update for IRBNet:**

For a completed research project that has undergone expedited review, the PI must submit Form G via IRBNet on or before the IRB approval expiration date. This will allow the IRB to close the active file. IRBNet will notify the PI of the expiration at least 6 weeks prior to expiration of IRB approval.

**F.1.3.1, 1<sup>st</sup> paragraph, 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> sentences, has been changed from:**

The application materials will be distributed to the IRB members at least 5 working days before the meeting. The PI must attend the meeting in which his or her application will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

**To state the following as a change in procedure and to update for IRBNet:**

The application materials will be distributed to the IRB members at least 5 working days before the meeting via IRBNet. The PI may attend the meeting in which his or her application will be reviewed. If the PI is a student, the faculty sponsor may attend as well.

**F.1.3.1, 2nd paragraph, 2nd sentence, has been changed from:**

The PI is responsible for submitting the required materials to the IRB administrator, care of OSP, by the deadline, typically 10 working days prior to a scheduled meeting.

**To state the following to update for IRBNet:**

The PI is responsible for submitting the required materials via IRBNet, by the deadline, typically 10 working days prior to a scheduled meeting.

**F.1.3.1, 3rd paragraph, 1<sup>st</sup> bullet, 2<sup>nd</sup> and 3<sup>rd</sup> sentences, has been changed from:**

The PI is sent a letter of approval and the informed consent or assent form with the “IRB approval” validation stamp. See Section J.1 for more information about the validation stamp.

**To state the following to update for IRBNet:**

A letter of approval and the informed consent or assent form with the IRB approval information will be posted in IRBNet. See Section J.1 for more information about the validation information.

**F.1.3.1, 3rd paragraph, 2<sup>nd</sup> bullet, 3<sup>rd</sup> sentence, has been changed from:**

If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson, as soon as possible.

**To state the following to update for IRBNet:**

If the PI does not have the additional information available at the meeting, the PI will forward this information via IRBNet to the IRB chairperson or IRB vice chairperson, as soon as possible.

**F.1.3.1, 3rd paragraph, 2<sup>nd</sup> bullet, 1<sup>st</sup> sub-bullet, 4<sup>th</sup> sentence, has been changed from:**

The PI would again need to be present at the meeting.

**To state the following as a change in procedure:**

The PI may be present at the meeting.

**F.1.3.1, 3rd paragraph, 3<sup>rd</sup> bullet, 2<sup>nd</sup> sentence, has been changed from:**

The PI is sent a letter describing the reasons the research application was not approved.

**To state the following to update for IRBNet:**

A letter is posted in IRBNet describing the reasons the research application was not approved.

**F.1.3.2, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI will submit Form D and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the modification request.

**To state the following to update for IRBNet:**

The PI will submit Form D via IRBNet and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the modification request.

**F.1.3.2, 2<sup>nd</sup> paragraph, 4<sup>th</sup> sentence, has been changed from:**

For modification requests, which can be reviewed under the expedited review process, see the modification request section (Section F.1.2.1) under expedited review process (Section F.1.2).

**To state the following to correct a typographical error:**

For modification requests, which can be reviewed under the expedited review process, see the modification request section (Section F.1.2.2) under expedited review process (Section F.1.2).

**F.1.3.2, 2<sup>nd</sup> paragraph, 8<sup>th</sup> and 9<sup>th</sup> sentences, has been changed from:**

The PI must attend the meeting in which his or her modification request will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

**To state the following to update for IRBNet:**

The PI may attend the meeting in which his or her modification request will be reviewed. If the PI is a student, the faculty sponsor may attend as well.

**F.1.3.2, 3<sup>rd</sup> paragraph, 1<sup>st</sup> bullet, 2<sup>nd</sup> and 3<sup>rd</sup> sentences, has been changed from:**

The PI is sent a letter of approval of the requested modifications. If the modifications involve the informed consent or assent form, the revised informed consent or assent form will also be sent with the “IRB approval” validation stamp placed on the form.

**To state the following to update for IRBNet:**

A letter of approval of the requested modifications is posted in IRBNet. If the modifications involve the informed consent or assent form, the revised informed consent or assent form with the IRB approval information will also be posted in IRBNet.

**F.1.3.2, 3<sup>rd</sup> paragraph, 2<sup>nd</sup> bullet, 3<sup>rd</sup> sentence, has been changed from:**

If the PI does not have the additional information, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson.

**To state the following to update for IRBNet:**

If the PI does not have the additional information, the PI will forward this information via IRBNet to the IRB chairperson or IRB vice chairperson.

**F.1.3.2, 3<sup>rd</sup> paragraph, 2<sup>nd</sup> bullet, 2<sup>nd</sup> sub-bullet, 2<sup>nd</sup> sentence, has been changed from:**

The PI would again need to be present at the meeting.

**To state the following to update for IRBNet:**

The PI may be present at the meeting.

**F.1.3.2, 3<sup>rd</sup> paragraph, 3<sup>rd</sup> bullet, 2<sup>nd</sup> sentence, has been changed from:**

The PI is sent a letter describing the reasons the modification request was not approved.

**To state the following to update for IRBNet:**

A letter is posted in IRBNet describing the reasons the modification request was not approved.

**F.1.3.3, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI will submit Form E and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the continuation request.

**To state the following to update for IRBNet:**

The PI will submit Form E via IRBNet and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the continuation request.

**F.1.3.3, 2<sup>nd</sup> paragraph, 4<sup>th</sup> sentence, has been changed from:**

For expedited reviews, see Continuation Review in Section F.1.2.2 under Expedited Review (Section F.1.2).

**To state the following to correct a typographical error:**

For expedited reviews, see Continuation Review in Section F.1.2.3 under Expedited Review (Section F.1.2).

**F.1.3.3, 3<sup>rd</sup> paragraph, 3<sup>rd</sup> sentence, has been changed from:**

A notification letter will be sent to the PI and, if appropriate, the funding agency.

**To state the following to update for IRBNet:**

A notification will be sent to the PI via IRBNet and, if appropriate, a letter will be sent to the funding agency.

02/17/11

Revised - **Section G**

**G.3, 2<sup>nd</sup> sentence, has been changed from:**

Additionally, the PI must submit Form F to the IRB administrator, care of OSP, as soon as possible thereafter, but no later than 5 working days after first awareness of the problem.

**To state the following to update for IRBNet:**

Additionally, the PI must submit Form F via IRBNet as soon as possible thereafter, but no later than 5 working days after first awareness of the problem.

**G.4, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> and 3<sup>rd</sup> sentences, has been changed from:**

If, based upon the level of risk to the research participants and the seriousness of the allegation, the decision is made that no formal investigation is necessary, the IRB chairperson or vice chairperson will provide a report to be filed with the confidential project records which details the allegation of problems, noncompliance, and any corrective actions. If, however, the determination is made that a formal investigation should be conducted, a subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member who is the community representative, and another IRB member, who holds tenure and is outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance.

**To state the following as an update in procedure and to update for IRBNet:**

If, based upon the level of risk to the research participants and the seriousness of the allegation, the decision is made that no formal investigation is necessary, the IRB chairperson or vice chairperson will provide a report to be posted within IRBNet and to be filed with the confidential project records which details the allegation of problems, noncompliance, and any corrective actions. If, however, the determination is made that a formal investigation should be conducted, a subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member who is outside the PI's department, and another IRB member, who holds tenure and is outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance.

**G.4, 2<sup>nd</sup> paragraph, 6<sup>th</sup> sentence, has been changed from:**

The IRB chairperson or vice chairperson will notify the PI in writing within 5 working days that an allegation of problem, adverse effect, or noncompliance was received.

**To state the following to update for IRBNet:**

The IRB chairperson or vice chairperson will notify the PI via IRBNet within 5 working days that an allegation of problem, adverse effect, or noncompliance was received.

**G.4, 3<sup>rd</sup> paragraph, 3<sup>rd</sup> sentence, has been changed from:**

The final report, which contains all identifying information, will be filled with confidential project records.

**To state the following to update for IRBNet:**

The final report, which contains all identifying information, will be posted within IRBNet and will be filed with confidential project records.

**G.5, 1<sup>st</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The chairperson or vice chairperson will promptly notify the PI(s), as well as the IRB administrator and CRO, in writing of this decision and the reason(s) for suspension of approval.

**To state the following to update for IRBNet:**

The chairperson or vice chairperson will promptly post a letter of this decision and the reason(s) for suspension of approval within IRBNet and provide an IRBNet message advising the PI(s), as well as the IRB administrator and CRO, of the posting.

**G.5, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The PI will be informed, in writing, of the outcome of the IRB meeting.

**To state the following to update for IRBNet:**

A letter will be posted within IRBNet with the outcome of the IRB meeting.

02/17/11

Revised - **Section H**

**H.2 has been changed from:**

All investigators must adhere to ISU's policy regarding intellectual property claims (see Appendix J of the University Handbook).

**To state the following to update the University Handbook information:**

All investigators must adhere to ISU's policy regarding intellectual property claims (see Section 370 of the *University Handbook*).

**H.4, 2<sup>nd</sup> paragraph, 3<sup>rd</sup> sentence, has been changed from:**

See Section O of this policy for a more detailed discussion of students as research subjects.

**To state the following to correct a typographical error:**

See Section P of this policy for a more detailed discussion of students as research subjects.

02/17/11

Revised - **Section I**

**2<sup>nd</sup> paragraph, 4<sup>th</sup> sentence, has been changed from:**

For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federalwide assurance), and each will review the research separately or designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement).

**To state the following to correct a typographical error:**

For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., Federalwide Assurance), and each will review the research separately or designate one of the institutions' IRBs to review the research (e.g., IRB authorization agreement).

**3<sup>rd</sup> paragraph, 1<sup>st</sup> sentence, has been changed from:**

When ISU is considered to be “engaged in research” (see OHRP guidance document “Engagement of Institutions in Research,” January 26, 1999) but the PI is not associated with ISU, the PI must submit the following for review by the IRB: an application (Form A, and Forms B or C, if applicable), a letter of support from a faculty member or EAP staff member at ISU who will sponsor the project, and a letter of approval from IRB of the institution where the individual is at, unless the individual's institution does not have an IRB.

**To state the following to correct a typographical error, update OHRP information, and update for IRBNet:**

When ISU is considered to be “engaged in research” (see OHRP guidance document “Engagement of Institutions in Research,” October 16, 2008) but the PI is not associated with ISU, the PI must submit the following for review by the IRB via IRBNet: an application (Form A, and Forms B or C, if applicable), a letter of support from a faculty member or EAP staff member at ISU who will sponsor the project, and a letter of approval from the IRB of the institution where the individual is at, unless the individual's institution does not have an IRB.

02/17/11

Revised - **Section J**

**J.1, 4<sup>th</sup> paragraph, 4<sup>th</sup> and 5<sup>th</sup> sentences, has been changed from:**

For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federalwide assurance), and each will review the research separately or designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement).

**To state the following to update for IRBNet:**

Once approved, the IRB will place IRB approval information on the approved informed consent or assent form. This information will include the IRB number, the approval date and the expiration date. The IRB number and approval and expiration dates must appear on the informed consent document. The PI may use the copy with the IRB approval information for distribution to potential subjects or the PI may type the information (i.e., “IRB#..., Approval date..., Expiration date...”) at the end of the informed consent form.

02/17/11

Revised - **Section N**

**N.1, 1<sup>st</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

The type of review required is determined by whether the research projects are intended to contribute to generalizable knowledge.

**To state the following to reflect a procedural change:**

The type of review required is determined by whether the research projects are intended to contribute to generalizable knowledge (please contact the IRB chair or vice chair for determination assistance).

**N.1.1, 5<sup>th</sup> paragraph, 3<sup>rd</sup> sentence, has been changed from:**

The instructor may require the student to complete the training program described in Section N.

**To state the following to correct a typographical error:**

The instructor may require the student to complete the training program described in Section O.

**N.1.1, 6<sup>th</sup> paragraph, 2<sup>nd</sup> sentence, has been changed from:**

If any harm to a subject has occurred, the instructor must report in writing to the IRB immediately and have the student cease research activities until a decision is made regarding continuation of the project.

**To state the following to update for IRBNet:**

If any harm to a subject has occurred, the instructor must report in writing to the IRB immediately (see Section G for details) and have the student cease research activities until a decision is made regarding continuation of the project.

02/17/11

Revised - **Section O**

**O.1, 3<sup>rd</sup> paragraph, 1<sup>st</sup> sentence, has been changed from:**

If any new investigator is added after the submission of the initial application or a continuation request, the PI must submit these names to the IRB administrator, care of OSP.

**To state the following to update for IRBNet:**

If any new investigator is added after the submission of the initial application or a continuation request, the PI must submit these names via IRBNet.

**O.2, 3<sup>rd</sup> paragraph, 1<sup>st</sup> sentence, has been changed from:**

No less than 30 days before the expiration of certification, the IRB administrator will inform individuals currently certified of the requirements for re-certification.

**To state the following to update for IRBNet:**

No less than 30 days before the expiration of certification, the individuals requiring recertification will be notified of the requirements for re-certification.

02/17/11

Revised - **Section P**

**P.1, 1<sup>st</sup> paragraph, 4<sup>th</sup> and 5<sup>th</sup> sentences, has been changed from:**

Projects in which students include other students in studies that are not designed for use beyond a course are not considered research as defined by federal regulations or this policy (e.g., administering a brief survey to students in the dining hall regarding food service). Although they are not covered in this section, these studies require review as set forth in Section M of this policy.

**To state the following to update for IRBNet:**

Projects in which students include other students from outside of their classroom in studies that are not designed for use beyond a course are not considered research as defined by federal regulations or this policy (e.g., administering a brief survey to students in the dining hall regarding food service). Although they are not covered in this section, these studies should follow guidance as set forth in Section N of this policy.

02/17/11

Added - **Section R**

Completely new 3 page section on Medical Devices.

02/17/11

Revised – **Appendices: Appendix 1**

Updated IRB Checklists and Forms for IRBNet.

01/31/11 Revised - **Question #8 on Form A1 – changed “university” to “institution”**

Students {If using students at your institution (e.g. ISU, RHIT, or VU), submit Form S with your application}.

Prior version stated:

Students {If using students at your university (e.g. ISU, RHIT, or VU), submit Form S with your application}.

01/31/11 Revised – **Form A2 – revised instructions to read:**

Provide responses to the following items in the textboxes provided, save document with your answers, and upload the completed Form A2 in IRBNet. If an item does not apply to your research project, simply indicate “Not applicable.” The completed Form A2 should not exceed 9 pages. Use a font size of 11 or larger. A proposal, thesis, or dissertation will not be accepted in lieu of responses.

Prior version stated:

Provide responses to the following items and submit your responses along with Form A. Each response should be numbered or labeled to correspond to the following items. If an item does not apply to your research project, simply indicate “Not applicable.” The research description (answers to all of the items below) should not exceed 5 type-written pages. Use a font size of 11 or larger. A proposal, thesis, or dissertation will not be accepted in lieu of responses.

01/31/11 Revised -**Form A1 – separated Forms A1 and A2 Research Description into separate documents and inserted text boxes into Form A2 to allow PIs to type responses directly onto form rather than having to create a separate document.**

04/21/10 Added - **Form S**

Added Form S to IRB website for PIs recruiting students on their own campus. Form is available to PI’s, but not required until July 1, 2010.

04/21/10 Revised - **Question #8 on Form A1**

Added Form A1 revision to IRB website.

Students {If using students at your university (e.g. ISU, RHIT, or VU), submit Form S with your application}.

Prior version stated:

Students

- 05/1/09 Revised - **Question #16 on Form A1**
- Added link for Annual Significant Financial Disclosure form.
- 02/25/08 Revised – **Section L. Internet Research; begin the paragraph with the following:**
- Non-exempt research using the Internet has unique characteristics that are not directly addressed by the Federal regulations.
- Prior version stated – Research using the Internet has unique characteristics that are not directly addressed by the Federal regulations.
- 02/25/08 Revised – **Section G.4 Investigations of Problems and Noncompliance; Paragraph 2 beginning with sentence 3**
- If , however, the determination is made that a formal investigation should be conducted, a subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member who is a community representative, and another IRB member who holds tenure and is outside the PI's department will...(paragraph continues as previously shown).
- Prior version stated – If, however, the determination is made that a formal investigation should be conducted, a subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member or alternate who is the community representative, and another IRB member, who holds tenure and is outside the PI's department will...(paragraph continues as previously shown).
- 10/17/07 Revised - **Question #15 on Form A1**
- Added N/A as an acceptable answer.
- 10/17/07 Added – **Question #18 to Form A1**
- Is this an internet survey?  Yes  No  
 If yes, what is the URL and password (if applicable)?  
 Please see Section L. (Internet Research) of the ISU Policies and Procedures Manual.
- 08/10/07 Revised – **Question #17 on Form A1**
- Do you directly or indirectly (spouses, parent, or child) hold an equity interest (stock, investment, bond) in the organization, or agency, or company where the research will be conducted?
- Prior version stated – Do you have a financial interest in the organization or agency or company for whom you work?

06/27/07 Revised - **Questions 2 & 3 on Form A1**

Institutional Email (required):

Prior version stated – Email

08/30/06 Revised – Section B.1- **Composition of the IRB and Appointment of Members**

Paragraph 1, Line 9, changed from “One member will be on the faculty of the Terre Haute Center for Medical Education of Indiana University” to “One member or alternate will be on the faculty of the Terre Haute Center for Medical Education of Indiana University.”

07/27/06 Corrected – Section N.1.2 – **Sponsor Responsibilities in Student Projects**

Paragraph 2 referred to wrong section of ISU policy. Corrected the paragraph to read “All faculty members or EAP staff who supervise any type of student project using human subjects must be trained in accordance with ISU policy, Section O.

05/03/06 Added - **Section Q. Charges for IRB Review Services, effective July 1, 2006 as follows:**

The number and complexity of human research protocols at Indiana State University have increased substantially in recent years. Each of these studies requires review and ongoing oversight by the Institutional Review Board (IRB), a process that is vital to the university’s ability to conduct research. Effective July 1, 2006, the charge for initial IRB review of a single protocol will be \$1000 for grant-funded projects not administered through the university. There will be no fee assessed for projects which are grant funded if the grant is administered by ISU. There will also be no fee for unfunded research conducted at the university. This will be a one-time fee, with no additional charge for the continuing (annual) review of a protocol, or for the processing of protocol amendments.

05/18/06 Revised – **Question #5 on Form A1 – Culminating Projects**

Previous version asked for a copy of committee approval for culminating projects. Revised as follows:

- culminating project (Does your department require committee review of culminating projects?)
  - Yes (Submit evidence of committee approval. Do NOT submit your culminating project proposal.)
  - No (Department does not require committee approval for culminating projects.)

02/17/06

**Section G.4 Investigations of Problems or Noncompliance  
Paragraph 2; begin the paragraph with the following:**

The IRB chairperson or vice chairperson may conduct an informal inquiry into allegations of problems or noncompliance to make the determination whether an investigative subcommittee should be formed. If, based upon the level of risk to the research participants and the seriousness of the allegation, the decision is made that no formal investigation is necessary, the IRB chairperson or vice chairperson will provide a report to be filed with the confidential project records which details the allegation of problems, noncompliance, and any corrective actions. If, however, the determination is made that a formal investigation should be conducted....(continues into paragraph 2 as previously shown).

01/19/05

**Manual Format** – Inserted blank page between each section to facilitate future revisions.

01/19/05

**Section B – Responsibilities and Actions of the Institutional Review Board  
B.6 Approval of Research – first sentence.**

Requirements to be met for approval are listed in the Reviewer Checklist in Appendix 2.

Prior version stated – Requirements to be met for approval are listed on Form H.

01/19/05

**Section F. – Process for IRB Review and Approval of Research, F.1.1.1 – New Application, paragraph 2, 3rd bulleted item, 2nd sentence.**

If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB chairperson, IRB vice chairperson, or designated IRB member, the application is considered for expedited or full review.

Prior version stated – If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB chairperson, IRB vice chairperson, or designated IRB member, the PI is contacted in writing or via e-mail and the application is considered for expedited or full review.

01/19/05

**Section L. Internet Research – Second page, Item 2 after “The following apply to all types of study materials”.**

The printed version of all information must carry the approval date and the date approval expires for the study as determined by the IRB.

Prior version stated – The printed version of all information must carry the approval and expiration of approval dates for the study as determined by the IRB.

- 01/19/05      **Appendix 1 – Instructions for Submitting Materials for Review by the Institutional Review Board** – Materials needing to be submitted has been changed from 3 copies to 1 copy.
- 01/19/05      **Appendix 5 – Training Procedures for Human Subjects Protection** – Updated with current instructions from the training facility.
- 08/16/04      **Section F.1.2.3 Continuation Request – Paragraph 2, beginning with sentence 3.**
- The IRB chairperson, IRB vice chairperson, or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via e-mail if a full review is needed. For continuation requests without proposed modifications or with only minor modifications that do not change the substance of the project, the level of risk to subjects, or the level of review required, the IRB chairperson, IRB vice chairperson, or a designated IRB member may conduct the review. For continuation requests with more than minor modifications proposed, the expedited review process timeline, and review actions are the same as for a new application.
- Prior version stated - The IRB chairperson or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via email if a full review is needed. The expedited review process, timeline, and review actions are the same as for a new application.
- 07/31/04      **Section O. 2 Who Must be Trained? - Paragraph 2**
- Initial certification is valid for three years. All investigators trained must renew certification every three years while working with human subjects. All IRB members and alternates must complete the certification when first appointed to the IRB; furthermore, they must participate in continuing education through IRB meeting activities.
- Prior version stated – Initial certification is valid for one year. All investigators trained must renew certification annually while working with human subjects. Similarly, all IRB members and alternates must renew certification annually while serving on the IRB.
- 07/31/04      **Appendix 5 – Training Procedures for Human Subjects Protection Paragraph 2, beginning with sentence 3**
- Initial certification and recertification are valid for three years. Should individuals allow certification to lapse, they will need to complete the core training.

Prior version stated – Initial certification and recertification are valid for one year. Should individuals allow certification to lapse, they have 24 months from the original certification date to recertify using the continuing education modules. If certification lapses for more than 24 months from the original certification date, they will need to complete the core training.