

## **Informed Consent Checklist (as of March, 2008)** **(Revisions are noted in Purple)**

[Note: The most current electronic version of this can be found at:  
<http://www.bgsu.edu/downloads/gradcol/file44764.doc>]

Informed Consent is a process. It must be conducted in language understandable to the persons being informed. Consent documents should be written in plain, everyday language and include the following. Note – not every project’s consent process will require every item from this checklist. Generally, those checklist items containing **bold and underlined** portions should be considered mandatory.

1. **On BGSU Letterhead or letterhead-equivalent text if on web pages or e-mails**, which includes the department of the researcher (P.I). **No letterhead – no final approval**
2. Consent written in **first and second person** perspectives (e.g., I, me, my, you, we). From the FDA Information Sheet on Informed Consent – “Consent documents are more understandable if they are written just as the investigator would give an oral explanation to the subject, that is, the subject is addressed as ‘you’ and the investigator as ‘I/we’. This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of the first person may be interpreted as presumption of subject consent, i.e., the subject has no choice.”
3. **Language at the level appropriate for the participants** (the mean adult reading level in the U.S. is 6-8<sup>th</sup> grade). Note - if you are working with children, reading level can change significantly between grades.
4. Explanation that the study is a **research** study or project.
5. Identify the researcher’s “**affiliation**” with the institution (e.g., graduate student, faculty, staff, undergraduate).
6. Explanations of the **nature, purpose, and duration of the study**. If it is experimental, participants must be informed of this.
7. Explanation of **procedures** to be employed in the study (i.e., exactly what the participants are expected to do) and the **time commitment** required of the participants to complete those procedures.
8. Description of **risks** (hazards, inconveniences, discomforts, stress) the participant may experience, as far as they are known and how they will be minimized. Alternatively, state if the risks are minimal (i.e., no greater than those encountered in normal daily life). Also, if appropriate, identify resources that participants can make use of to help them deal with emotional distress, etc.
9. **Benefits** of the study in general (scholarly) and benefits to participants as individuals. All studies must have some benefit in order to receive HSRB approval. If participants will not get any direct benefit from their participation, it is appropriate to include language to that effect as well.
10. How **confidentiality** will be maintained and any limits to confidentiality. **Any wording that “guarantees” confidentiality or anonymity is not appropriate.** Also, if appropriate, indicate any limitations to confidentiality (for example, in situations where participants may be quoted – how quotes will be attributed to them; if excerpts of audio or video recordings will be included as part of presentation of study results – possibility that participants might be identifiable to viewers of the recordings).

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

11. That participation is voluntary and that the participant can withdraw her/his consent or discontinue participation in the research at any time without penalty.
12. Contact person(s). Include the researcher's name, telephone number, and e-mail address (students must include faculty advisor's equivalent contact information). Include the following statement relative to HSRB contact: "If you have questions about the conduct of this study or your rights as a research participant, you may contact the Chair of Bowling Green State University's Human Subjects Review Board at (419) 372-7716 (hsrb@bgsu.edu)." Alternate wording could be: "You may also contact the Chair, Human Subjects Review Board, Bowling Green State University, (419) 372-7716 (hsrb@bgsu.edu), if any problems or concerns arise during the course of the study."
13. A place for **signature of the participant and date if obtaining written consent**; witness line should be included ONLY if required. Please note that the researcher is not a valid witness to the process of consent. (If you need assistance in making this determination, contact the HSRB). Some researchers make provision to capture the signature of the person from the research team who obtained consent. In those cases that signature line is clearly labeled as such (e.g., "Signature of person obtaining consent")
14. If the signature portion of the form is intended to be a "tear off" for your records, make sure it has at least the project title on it so you can associate consent forms to their projects (in the event you are conducting multiple projects).
15. That the **participant will be provided with a copy of the consent document(s)**, including, if s/he wishes, the signed consent form.
16. **NO use of "understand" phrases (e.g. "you understand," "I understand")** – Substitute "I have been informed", "It has been explained to me" or words to that effect. *Note – try to limit the number of times sentences and paragraphs of consent documents being with the "I have been informed" phrase.*
17. *For surveys for which written consent is not obtained (e.g., consent information is provided as a cover sheet / information page with no provision for participant signature), that completion and return of the survey indicates consent to participate.*
18. No language that would release or appear to release the researcher, the institution or its agents from liability for negligence (no exculpatory language).
19. If appropriate, that any significant new findings affecting risks will be reported to the participant.
20. If audio or videotaping is involved, the uses to which the tapes may be put, who will have access to them, how they will be secured and how long they will be retained by the researcher (ultimate disposition).
21. If participant(s) is non-English speaker, consent documents should be in his/her native language.
22. If appropriate, debriefing procedures.
23. If appropriate, circumstances under which the P.I. may terminate subject participation without subject consent.
24. Conditions of participation such as age, health status, etc.
25. If the study is therapeutically related, disclosure of alternate procedures the subject might choose.

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

26. The following statement, if there are possibilities of physical risk: “As in all research, there may be unforeseen risks to you as a participant. If an accidental injury occurs, appropriate emergency measures will be taken.”
27. If you are using focus groups, remind focus group participants to keep confidential the information discussed during the session(s). This is particularly important when sensitive topics are discussed.
28. If you are obtaining consent or participant information (e.g., survey responses, indications of interest in participation) via e-mail, you should inform participants that e-mail is not 100% secure.
29. If you are conducting a web-based survey, remind participants that they should clear the browser cache and page history.
30. If there is a possibility that your participants could be completing a web-based survey at work, remind them of the possible use of tracking software by their employer.
31. **Do not** include language in your consent document(s) indicating that the project has been reviewed and/or approved by the HSRB as this could be coercive. If you wish, you can inconspicuously include the HSRB project ID on the document(s).
32. Approximate total number of participants who will be enrolled in the study. If you are offering entry into a drawing or raffle as a participation incentive, provide some indication regarding the chances of winning. Base this upon your planned number of enrollees.
33. Any additional costs to the participant that may result from participation in the research.
34. If appropriate (e.g., subjects are students, members of an organization, etc.), that the decision to participate or not participate will have no impact on grades, class standing, or relationship to the institution in any way.
35. If working with adults, language stating that individuals must be 18 years of age or older to participate in the study.

**Common consent form word usage with corresponding alternatives**

A major component of the informed consent process is language at an appropriate level for study participants. Following is a table that may be used as a reference tool to help translate complex words/phrases into simpler wording for average reading level requirements.

<b>Complex words/phrases</b>	<b>Simpler words/phrases</b>	<b>Easy words/phrases</b>
additional	extra	more
administer	dispense	give
adverse	negative	bad; harmful
appropriate	suitable	proper; right
approximately	nearly	about

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

available	present	handy
categories	classes	groups
combination	series	mix
compensation	payment	money
consequences	outcomes	results
empirical evidence	research	study
equivalent	equal	same
immediately	at once	now
initiate	begin	start
medications	medicines	drugs
unique identifying information	personal information	IDs

**Readability – Examples of increasing language complexity based on grade levels as determined by the Flesch – Kincaid Scale (available in MS Word)**

4<sup>th</sup> grade – You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your grades. Your teacher's attitude toward you will not change.

6<sup>th</sup> grade – Taking part in this study is your choice. If you decide not to take part, this will not harm your relationship with your teachers or with the university.

8<sup>th</sup> grade – Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

10<sup>th</sup> grade – Your participation in this study is voluntary and you are free to withdraw at any time. Participation or withdrawal will not affect any rights to which you are entitled.

12<sup>th</sup> grade – Your participation in this study is strictly voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without prejudice to your future benefits or other services to which you are otherwise entitled.

College – You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your relationship to the university.

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

**SAMPLE WORDING FOR ELEMENTS OF CONSENT**

4. **Research Study Language**

- “You are invited to be in a research study on (topic goes here). As part of my work on (name of degree or project) in the Department of (name of department), I am conducting a research study of (describe study participants or topic).”

6. **Nature, purpose and duration of study**

- “This study is being conducted for (dissertation, thesis, class project, etc. goes here). The purpose of this study is (describe study purpose in a few sentences, using language that is appropriate for the study participants).

7. **Procedures**

- “This study will ask/request you to (list and thoroughly explain all activities requested of the participant from start to finish of study).”
- “This study involves (list and thoroughly explain all activities requested of the participant from start to finish of study).”
- For studies where there is a single contact with a participant: “I / we estimate that your participation will take approximately (describe length of participation). Your participation will involve (describe activities, such as completing a survey, participating in a focus group, being observed in a certain activity, being interviewed, etc.).”
- For studies where there are multiple contacts with a participant: “I / we estimate that your initial participation will take approximately (describe length of participation). Your initial participation will involve (describe activities, such as completing a survey, participating in a focus group, being observed in a certain activity, being interviewed, etc.). Subsequent participation will involve (describe other stages of the study and activities). The estimated total amount of time for your participation is approximately (describe total length of time).”

8. **Risks**

- For minimal risk studies: “The anticipated risks to you are no greater than those normally encountered in daily life.”
- For greater than minimal risk studies: “Your participation in this study may result in (list possible risks or discomforts). Precautions will be taken to minimize these risks. In case of injury or severe adverse reaction (indicate if medical or psychological care is available, by whom, and where).” [Note – this last sentence would only be relevant for situations/studies where there is risk of physical injury or psychological distress]

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

9. **Benefits**

- “This study may benefit (describe the reasonably expected benefits to the participants and others).” Also indicate any alternatives to the research’s diagnostic method or treatment, if appropriate.

10. **Confidentiality**

- “Information you provide will remain confidential and your identity will not be revealed.”
- “I/we will protect the confidentiality (replace with the term anonymity if response data can in no way become associated with any respondent and it is not possible to conduct a follow-up) of you as a respondent and your responses throughout the study and publication of study results.”
- “Only members of the research team will have access to the data / information you provide.”
- “Your identity will not be revealed in any published results unless you specifically request identification.”
- Include a description of the way(s) in which confidentiality will be protected – e.g., data stored in locked filing cabinet / password protected database; results will be presented only in summary manner.
- If the project involves the use of video or audio recording, include a discussion of the manner in which the recordings will be secured/stored and what the ultimate disposition of the recordings will be (e.g., retained indefinitely, erased or destroyed after some period of time, etc.). For example - “Recordings of the (focus group / interview) will be stored (describe storage considerations) and will be (describe ultimate disposition of the recordings).”

11. **Voluntary participation and ability to withdraw from the study**

- “Your participation in this study is completely voluntary, and you can refrain from answering any questions without penalty or explanation.”
- “You are free to withdraw consent and to discontinue participation in the project at any time.”
- “If you decide to participate and change your mind later, you may withdraw your consent and stop your participation without penalty or explanation.”
- In some situations, such as projects in which “participation” simply entails providing consent for the use of materials (such as classroom work products, reflection papers, etc.) that were produced by the individual, consider putting a reasonable limitation on when consent can be withdrawn (to avoid situations, such as where a manuscript reporting the results of the project has been accepted for publication and now a participant wants to withdraw consent).

12. **Contact information**

- “If you have any questions or comments about this study, you can contact (“me” or researcher name) at (phone number, e-mail address) or (advisor name), my project advisor, at (phone number, e-mail address).”

17. **Completion as consent**

- “By completing and returning this (questionnaire; survey) you are indicating your consent to participate in the (study; project).” For online (i.e., web-based) surveys and questionnaires – “By completing this

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

(questionnaire; survey) and submitting it (or clicking the “submit” button) you are indicating your consent to participate in the (study; project).”

**28. Security of e-mail**

- If using e-mail to recruit potential subjects – “Please note that e-mail is not 100% secure, so it is possible that someone intercepting your e-mail will gain knowledge of your interest in the study.”
- If using e-mail as a mechanism to receive completed data collection instruments – “Please note that e-mail is not 100% secure, so it is possible that someone intercepting your e-mail will have access to your (questionnaire; survey) responses.

**29. Clearing browser cache and page history**

- “Please remember to clear your browser’s cache and page history after you submit the (questionnaire; survey) in order to protect your privacy.”

**30. Employer use of tracking software**

- “Some employers use tracking software to monitor and record keystrokes, mouse clicks, and web sites visited. This could impact the confidentiality of your responses. Therefore, you may wish to complete the (questionnaire; survey) on your home computer or a public computer.”

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

**Suggested outline of consent form**

- I. Purpose/Benefits
  - A. What is your relationship to the institution - undergraduate, graduate student, faculty, staff?  
In what department?
  - B. Is study being conducted for class project, thesis, dissertation, personal interests, or other reasons?
  - C. Study will examine what? Results will provide information regarding what and benefiting whom?
- II. Procedure
  - A. What exactly will participants be required to do during the study? Will they be audio or video taped at any time?
  - B. Are any incentives offered for participation? If so, what are they?
  - C. Are there any screening/selection/exclusion criteria that would determine whether someone could participate in the project? If so, what are they?
  - D. Emphasize voluntariness of participation.
- III. Time required
  - A. Are there multiple sessions/meetings with participants, or only one? How much time will each session/meeting take? How much total time will participation require?
- IV. Risks
  - A. Are there any risks associated with the study (hazards, inconveniences, discomforts, stress)? If so, how will they be minimized? If not, risks are no greater than those encountered in daily life.
- V. Participant's rights as a subject
  - A. Will information remain anonymous, confidential, or will participants be identified? How will the researcher maintain confidentiality (include considerations relative to data storage/security and dissemination of results)?
    - i. If audio or video taping will occur, indicate also the ultimate disposition of the tapes (e.g., destroyed at end of study, retained for some period of time before destruction, retained indefinitely).
  - B. Are there any limits to confidentiality? If participants will be quoted? If so, will they be quoted without attribution?; with attribution to a pseudonym?; with attribution to their real name?

**Informed Consent Checklist (as of March, 2008)**  
**(Revisions are noted in Purple)**

- C. Participants may withdraw from the study at any time or refuse to take part in any activity in which they feel uncomfortable. If there are consequences associated with withdrawal from the study, what are they? If there are circumstances under which the PI may terminate participation without subject consent, what are they?
- D. Have the right to have all questions concerning the study answered by the researcher.
- E. May request a summary or copy of the results of the study.
- F. Will be provided with/should retain a copy of the consent document for their records.
- VI. Contact information of researcher and advisor for questions about study
  - A. Names, phone numbers, and e-mail addresses of researcher (and advisor) if questions arise about the study itself (procedure, what is required of participants, how much time commitment).
- VII. Contact information for HSRB for questions or concerns about rights as a research participant
  - A. HSRB location, phone number, and e-mail address for questions concerning research participant rights.
- VIII. Signature and date lines (if obtaining written consent)
  - A. Include a statement of what it means if the participant signs the form (e.g., s/he has read the document, had his/her questions answered and agrees to participate in the study).
  - B. Places for the participant to sign and date the consent form.