

# Helpful Handouts for Submitting a Protocol for Research with Human Subjects

## Contents:

Definitions and Useful Links .....	page 1
Creating a New Protocol in Streamlyne	
The Protocol Tab .....	page 2
The Personnel Tab .....	page 5
Streamlyne Protocol Submission Questionnaire .....	page 6
Questionnaire for protocols using existing data .....	page 13
Adding Attachments .....	page 16
To SUBMIT the protocol for Review .....	page 18
 Sample Informed Consent forms	
1 <sup>st</sup> example, simple parental consent .....	page 19
2 <sup>nd</sup> example, parental consent in conversational form .....	page 20
3 <sup>rd</sup> example, adult consent in question/answer format.....	page 22
 OHRP Tips on Informed Consent .....	page 24
Checklist of Basic Required Elements of Informed Consent .....	page 26
Guidelines for altering or waiving informed consent requirements.....	page 27
 List and explanation of Exempt Research Categories .....	page 28
List and applicability of Expedited Research Categories .....	page 33

## Useful Definitions:

**IRB:** An Institutional Review Board established in accord with and for the purposes of reviewing research involving human subjects which falls under the jurisdiction of the Code of Federal Regulations, specifically 45 CFR 46.

**Human subject:** A *human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.  
(45 CFR 46.102 (e)(1))

**Research:** *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.  
(45 CFR 46.102 (l))

## Useful Links:

UA-Fayetteville's Research Integrity & Compliance Department website:  
<http://rsic.uark.edu>

Streamlyne Instructions:  
<http://streamlyneinfo.uark.edu/>

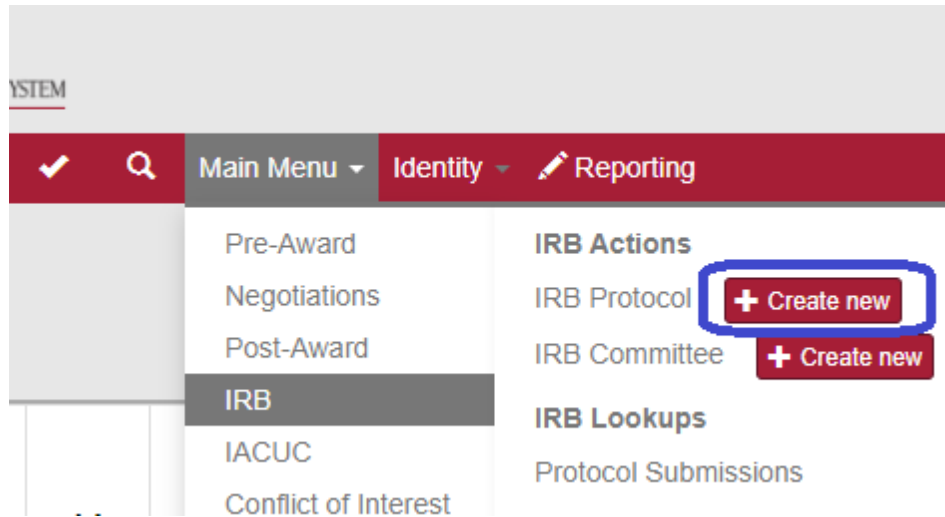
Training in the protection of human subjects:  
<https://www.citiprogram.org/>

## IRB Contact information:

Iroshi (Ro) Windwalker, CIP  
Institutional Review Board Coordinator  
Research Integrity & Compliance  
105 MLKG Building  
Fayetteville, AR 72701  
Ph. 479.575.2208  
Fax 479.575.6527  
[irb@uark.edu](mailto:irb@uark.edu)

## Creating a New Protocol:

Click on Main Menu -> IRB -> click the **+Create new** button next to the words IRB Protocol:





You will see the following screen, and the fields with an asterisk \* must be filled out.

The image shows a web form for creating a protocol. On the left is a sidebar with navigation items: Protocol (selected), Personnel, Questionnaire, Special Review, Permissions, Notes & Attachments, Protocol Actions, and Streams. The main content area has a red header 'Protocol' and a sub-header 'Document Overview'. Below this are several input fields: '\* Description' (text box), 'Explanation' (text box), 'Organization Document Number' (text box), '\* Protocol Type' (dropdown menu with 'Exempt' selected), '\* Principal Investigator' (text box with 'Person Lookup' and a search icon), '\* Title' (text box), and '\* Lead Unit' (text box with a search icon). A legend indicates '\* Indicates required field'. At the bottom is a red bar with a right-pointing arrow and the text 'Status & Dates'.

The person primarily conducting the study should be listed as the Principal Investigator, even if they're a student. To enter the Principal Investigator, click on the magnifying glass next to Person Lookup, which takes you to this search page:



**Person Lookup**

Person Id:   

First Name:

Email Address:

Active:  Yes  No  Both

Campus Code:   

Last Name:

User Name:



Office Phone:

Home Unit:

[Search](#) [Clear](#) [Cancel](#)

Only fill in ONE field (if multiple fields fill in on their own, then you have auto-fill set on your browser. This will cause you problems in the search, so turn it off. The results of the search will show up UNDERNEATH the red buttons. When you get a result, click on 'Return Value' to return it to your protocol:



**Person Lookup**

Person Id:   

First Name:

Email Address:

Active:  Yes  No  Both

Campus Code:   


Last Name:

User Name:

Office Phone:

Home Unit:

[Search](#) [Clear](#) [Cancel](#)

Return Value	Person Id	Full Name	User Name	Email Address	Directory Department	Directory Title
 return value	167602	Ro Windwalker	iwindwal@uark.edu	iwindwal@uark.edu	RSCP	Compliance Coordinator

One item found.

The other items on the Protocol tab that must be filled in are Funding Source and Participant Types:

▼ Funding Sources

Funding Sources ⓘ

	* Funding Type	* Funding Number	* Source	Title	Actions
Add:	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>
1	Internally Funded/Unfunded Research	none	none		<input type="button" value="Delete"/>

▼ Participant Types

Participant Types ⓘ

	* Type	* Count	Actions
Add:	<input type="text" value="select"/>	<input type="text"/>	<input type="button" value="Add"/>
1	Adults	<input type="text" value="25"/>	<input type="button" value="Delete"/>
Total Participants:		25	

If you have funding through OSP (Office of Sponsored Programs), you will choose “Externally Funded”, which will link you to the grants side of Streamlyne and allow you match up grant proposals with the IRB protocol. If you do not have funding, or you have departmental funding or funding that did not go through the OSP department, then you will choose “Internally Funded/Unfunded” and fill in the text boxes of Funding Number and Source. If you have no funding, you can put N/A in both of those boxes. **Don’t forget to click ADD** at the end of the row, or the information will not save into your protocol.

Choose the type of participant you have, the **MAXIMUM NUMBER** of participants that you might possibly enroll, and again, click add at the end of the row. You can have multiple types of participants, for instance, if you are surveying both students on campus and adults off campus, you will add both UA Students and Adults into your Participant Types.

## Completing the Personnel Tab:

Even if you are the only investigator in the study, you still have something that needs to be updated on the Personnel Tab.

The screenshot shows the 'Personnel' tab in a web application. On the left is a navigation menu with items: Protocol, Personnel (highlighted), Questionnaire, Special Review, Permissions, Notes & Attachments, Protocol Actions, and Streams. The main content area is titled 'Protocol Personnel' and contains a search bar for 'Person User Name' with a magnifying glass icon. Below this is a table with columns for '\* Person', 'Unit', and '\* Protocol Role'. An 'Add:' button is present. A dropdown menu is open for the 'Protocol Role' column, showing options: 'select', 'Co-Investigator', 'Data Integrity Manager', 'Principal Investigator', and 'Study Personnel'. Below the table, there is a red bar for 'Ro Windwalker' with the role 'Principal Investigator'. A 'Hide' button and 'Person Details' link are visible. At the bottom, there are dropdowns for 'Protocol Role' (set to 'Principal Investigator') and '\* Affiliation Type' (set to 'select'), along with an 'Update View' button. A notification at the top says 'Document was successfully saved.' and a note indicates '\* Indicates required'. Two blue arrows point to the search bar and the 'Affiliation Type' dropdown.

First, click on the red bar with your/the investigator's name, then click on the Show button for Person Details. Fill in the Affiliation Type. If you are a Student Investigator, then another investigator must be listed with the Affiliation Type of Supervisor.

To add more study personnel, click on the magnifying glass next to the Person User Name. This will take you back to the Person Lookup page, which works exactly the same way it did when you were entering the Principal Investigator. Choose the Protocol Role, and click Add, then click on the red bar with their name and add their Affiliation Type as well.

If you are collaborating with investigators who are not affiliated with UA, you will not be able to add them into the study personnel on the Personnel tab, as Streamlyne will only have personnel who are in Workday in the UAF, UADA, and UALR systems. Unaffiliated investigators can be added in a Note in the Notes & Attachments tab (their name and contact information will be needed.)

## Completing the Questionnaire Tab for Most Protocols:

### Human Subjects Research Interview (Incomplete)

Questions [Print](#)

What is the purpose of this research? Please explain both why you are doing the research (class assignment, thesis, etc.) AND/OR state your hypothesis. See attachment is not a sufficient response.

Answer this with both the purpose the data is being collected, e.g., class assignment, scholarly work (publication, thesis, etc.), internal quality assurance/quality control, but ALSO what it is you want to know, what you're looking for, what question you're trying to answer with this research.



0 of 5000

Are you collecting data about living individuals?

Yes  No

Are you collecting data through intervention or interaction with these individuals?

Yes  No

First you need to tell us WHOM you are asking to participate. If you're working with students in a 5<sup>th</sup> grade class at Springdale Elementary, for example, you will have marked "Children" as your Participant Type, but this is where you tell us WHICH children you're working with. If you want to interview CEOs of a particular type of company, then your Participant Type would have been Adult, but tell us WHICH adults you want to interview/survey/do research on. If you're just surveying random adults down on Dixon Street or on the internet, you would check No.

Beyond the basic Participant Types (children, UofA Students, adults, etc.) named elsewhere in this application, do you have a target population (particular group of people) you want to recruit? Some examples might be students in a particular class, members of a particular group or network, people in a specific age range (whether adult or minor), children in a particular school or class, etc.

Yes  No

Describe your target population.

0 of 2500

How are you recruiting participants? Are you standing in a public place asking people to take a survey, sending out introductory emails, posting an ad or blurb on a website or social media, posting a flyer in a public location, etc.? \*\*Please note that all recruitment materials will need to be uploaded in the Notes and Attachments section.

0 of 4000



This is where you tell us WHAT you're doing. If you're conducting a survey, doing interviews, having participants come into a lab and run tests, or measuring how long they can do a set of jumping jacks: detail exactly what you're asking them to do in the Procedures. If you are collecting data ABOUT people, then explain what data you're collecting and what you're doing with it.

**Provide a brief description of the procedures involving the participants.**

0 of 5000

**How long are the procedures likely to take? Include duration and frequency.**

I don't need to know that you expect to be working on this for four months. How much of your participant's time are you taking up?

0 of 4000

**How will information be given to people to get their informed consent to participate in this research? Answers should include specific methods (e.g., verbal consent, information handout, online consent form, full consent form requiring signature documentation.) \*\*Please note that consent materials -- from a script for verbal consent to full consent forms that require participant signature -- must be uploaded in the Notes and Attachments section.**

0 of 2000

**Does data collection rely on a scheduled event, such as a convention or specific date?**

Yes  No

**Provide the date or date range, and the name of the event.**

0 of 1000

Tell us how you're collecting, storing, and securing your data:

How will your data be collected? Include all that apply: online, on paper/in person, audio and/or video recordings. \*\*Please note that all data collection materials will need to be uploaded in the Notes and Attachments section. This includes: surveys, questionnaires, interview questions or anything that is given to or asked of a participant.

Please include whether you are collecting identifying information or only anonymous data here.



0 of 2000

How will your data be stored? Include all that apply: electronically, on paper, audio and/or video recordings.

If you are collecting identifying information, such as consent forms, but removing identifiers from the data when you store it, please clarify that here or in the Data Security question below.



0 of 2500

How will that data be kept secure?



0 of 2000

Risks and benefits to the participant are very important when reviewing a protocol.

**Minimal Risk is defined as risks of harm not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Will participants be exposed to more than minimal risk? Include in your consideration the potential of mental risks if asking sensitive questions, or legal or reputational risks in case of breach of confidentiality.**

Risks to the participant can include being upset by disturbing or personal questions on a survey, or the risk of personal information getting out, even personal opinions (such as whether their boss is horrible) can be a risk of harm to a participant in a simple survey.

Yes  No

**Describe the risks in question and any precautions that will be taken to minimize those risks.**

0 of 2500

**Are there any direct benefits to the participants for participating in this study?**

Benefits can include if you're paying them money, giving credit in a class for participating, or even learning more about themselves by taking psychological surveys.

Yes  No

**Describe the benefits participants will or may receive.**

Be aware that in order to prevent coercion, when a research protocol offers class credit for participation, there must also be another method for students to receive the same credit for their class if they choose not to participate, and this should be specified both here and in the consent form.

0 of 2500

**Will the proposed research involve deception or the withholding of information from participants?**

Yes     No

---

**Will the proposed research necessitate medical clearance from a physician prior to participation?**

Yes     No

---

**Will the proposed research involve gathering biological samples (blood, tissue, etc.)?**

Yes     No

---

**Will the proposed research involve administering of substances or providing food and drink, other than water, to participants?**

Yes     No

---

**Will the proposed research involve physical exercise or conditioning?**

Yes     No

---

Does the research require review by a non-UofA IRB?

If you are collaborating with a researcher at another institution, be sure to check if they have an IRB that they are required to submit the protocol to. If so, mark Yes at this first question, and it will tell you where to go to tell us what IRB will be reviewing the study.

Yes  No

Please provide on the Protocol tab, Additional information > Other Identifiers section, all pertinent information regarding the submission to the External IRB(s). Please type 'ok' in the text box to verify your understanding.

0 of 2

Does this research require approval from another institution or agency, such as a school or privately owned business?

If you are doing research at a school or private business, you will need to get approval to conduct your research using their facilities before we can approve the protocol.

Yes  No

In the Notes and Attachments section, please upload documentation confirming the approval of the agencies or institutions involved. Please type 'ok' to verify your understanding.

0 of 2

## Completing the Questionnaire Tab for Studies with Existing Data:

Are you collecting data about living individuals?

Yes  No

Are you collecting data through intervention or interaction with these individuals?

Yes  No

Do you have access to identifiable private information about these individuals?

Yes  No

**It appears that this project does not involve Human Subjects. Please type 'ok' in the text box, then save and submit your protocol for IRB verification.**

0 of 2

If you do not have access to private, identifiable information, then you're not doing research with Human Subjects.

Do you have access to identifiable private information about these individuals?

Yes  No

What data are you collecting?

0 of 2000

Is the data publicly available?

If you have to fill out an application or request access to the data, rather than just clicking on a link to download it, then it is NOT publically available.

Yes  No

Please upload a copy of the data use application or agreement in the Notes and Attachments section. Please type 'ok' to verify your understanding.

0 of 2

If you DO have access to identifiable information, tell us what that data is. If you have to fill out an agreement or application to get that data, we will need to see a copy of that completed application/agreement.

Is the data publicly available?

Yes  No

Is the data accessible online?



Yes  No [OR...](#)

Please cut and paste the URL or URLs.

0 of 2500

Is the data accessible online?



Yes  No

Explain how/where one can obtain the data to verify its availability.

0 of 2500

If it IS publicly available, we will need to know where you're getting it from, in order to verify that.



## Adding Attachments in the Notes & Attachments Tab:

Everything that participants will see as part of the research, from the initial contact for recruitment through any post-participation debriefing, must be uploaded into the Attachments section of the protocol for review. This includes not just actual documents such as consent forms or flyers that will be posted around campus, but also scripts for verbal recruitment such as telephone calls, in-person recruitment, or interview introductions, or text of emails that will be sent out, either as recruitment, or form emails over the course of the study to remind participants of the second phase, ask them to take part in a follow-up interview, etc.

Beyond participant materials, other items that may need to be included in the Attachments are any agreements connected to the research (data use agreements, permission to conduct research at a particular location, etc.) or documentation about any medical devices that may be used in the study.

Protocol

Personnel

Questionnaire

Special Review

Permissions

**Notes & Attachments**

Protocol Actions

Streams

Document was successfully saved. X

\* Indicates required

Protocol Attachments (0)

Add Protocol Attachment

\* Attachment Type : select

Status : select

Complete

Incomplete

Email :

Comments :

\* File Name : Browse...

Contact Name :

Phone :

\* Description :

Add

To upload your attachment, first select the Attachment Type. Your options will be: Adverse Event Summary, Authorization Agreement, Consent Materials, Data Collection Materials, Data Use Agreement/Memorandum of Understanding, Debriefing Materials, Medical Clearance Documentation, Modification Summary, Other Approvals, Protocol, and Recruitment Materials.

PLEASE NOTE that if you choose the wrong Attachment Type, it will NOT affect your review or approval, so don't stress over this. Having said that, a new protocol submission will likely not ever need an adverse event summary or a modification summary; it might possibly need any of the other categories. Also, an Authorization Agreement is a document that is entered into between two institutions when a protocol is covered by more than one IRB, to allow one IRB to review the protocol and the other to accept their review. Generally the researcher would not be the one uploading an authorization agreement; the IRB Coordinator usually uploads the authorization agreement into the attachments of a protocol after it is completed and signed by both institutions.

Of the remaining attachment types that you are more likely to use, but not be sure about:

- Consent Materials would include anything involving the consent process, whether that is a verbal script, an informational handout, or the actual consent form requiring signature. (NOTE: You should NOT have signed consent forms at the time of protocol submission, as you should not be contacting participants before protocol approval, but if you do, or if you are submitting an amendment or a renewal, you should NEVER upload signed consent documents into the Streamlyne system.)

- Data Collection Materials are anything by which you are collecting data: this can be the obvious surveys, but it can also be a list of interview questions that you're going to be asking, or a list of data points that you are checking off when observing a classroom. It can also be the list of data points that you are going to be collecting from a medical record or other existing dataset.
- A Data Use Agreement/Memorandum of Understanding is generally only used when you are doing work with an existing dataset, and is a contract whereby you agree with the owner of the dataset for the limit of use.
- Debriefing Materials would be anything that you say or hand out to your participants after they have completed their participation. PLEASE NOTE that not all studies have to have all categories of documents; most protocols do not have debriefing materials, and that is fine.
- Protocol – If you have a separate protocol for your study, this is what it would be submitted as, or a document giving an overview or timeline for the overall research.
- Recruitment Materials: everything that the participant will see/hear/interact with as part of the research up until they have consented to participate, so this will include any scripts, if you are calling or otherwise speaking to them in person, texts or emails to be sent out, social media advertisements, flyers, etc. This also includes screening surveys and any form emails that will be sent out scheduling the first contact.

Once you have chosen the Attachment Type, set the Status of the document to COMPLETE. (You can upload a document as Incomplete, but it will give you an error if you submit the protocol with an Incomplete document in the Attachments.) Enter a description of the document in the Description box to explain what the document is and what it will be used for. You can also enter information in the Comments box, but the information in the Description box is what will show in the list of the Attachments once they are uploaded, without clicking on each file to pull up their details. Then click the Browse button to find the file in your system to upload. Once you have chosen the correct file to upload, click ADD.

This can be repeated as many times as necessary to upload all of the information/documents that are needed for your study.

## Submitting the Protocol for Review:

The screenshot shows a web interface for submitting a protocol for review. On the left is a navigation menu with items: Protocol, Personnel, Questionnaire, Special Review, Permissions, Notes & Attachments, Protocol Actions (highlighted in red), and Streams. The main content area has a red header 'Request an Action' and a sub-header 'Available Actions'. A 'Submit for Review' button is visible. A blue arrow points down to the 'Submit for Review' button. Below this, there are two dropdown menus: '\* Submission Type : Initial Protocol Application for Approval' and '\* Submission Review Type : Exempt'. A blue arrow points to the 'Exempt' dropdown. Underneath is a 'Type Qualifier : select' dropdown. A section titled '\*Checklist (Exempt)' contains a list of checkboxes with descriptions of research types. A blue circle highlights the 'Exempt' dropdown and the checklist section. A yellow text box with a blue arrow pointing to it contains the text: 'The Submission Review Type and Checklist are NOT IMPORTANT, because I will change this information during the review process if necessary. Just choose whatever you think best fits your study, and don't worry about getting it wrong.' At the bottom right is a red 'Submit' button. A notification at the top says 'Document was successfully saved.' and a note on the right says '\* Indicates required'.

Once you have clicked that Submit button, the protocol will be routed to any other investigators listed on your protocol to approve the submission, and then it will go to the IRB Coordinator for review.

Co-Investigators and/or Faculty Supervisors can approve the submission by opening it, clicking on Protocol Actions, scrolling to the bottom of the page, and clicking the red Approve button.

## INFORMED CONSENT

*Title:* Title of your study

*Researcher(s):*

Ronald A. Researcher  
Don. A. Advisor, Ph.D., Faculty Advisor  
University of Arkansas  
College of Everything Important  
Department of All the Good Stuff  
100 Important Building  
Fayetteville, AR 72701-1201  
479-575-0000

*Compliance Contact:*

Ro Windwalker, CIP  
Compliance Coordinator  
Research Integrity & Compliance  
University of Arkansas  
105 MLKG Building  
Fayetteville, AR 72701-1201  
479-575-2208  
irb@uark.edu

*Description:* The present study is an action research project designed to investigate what effects explicit instruction may have in increasing vocabulary achievement in a second grade classroom. Explicit instruction incorporates direct teaching strategies to specifically address an academic issue. At the beginning of the study your child's vocabulary achievement will be assessed using a teacher created assessment. Explicit vocabulary instruction will be taught for 30 minutes a day, four days a week, for nine weeks. Observational records will be recorded daily on the progress of the students. Following the intervention your child's vocabulary achievement will be assessed again using the teacher created assessment. This will be done in order to determine what effects explicit instruction may have had on vocabulary achievement.

*Risks and Benefits:* There are no risks, other than those associated with regular classroom instruction, anticipated with this project. The potential benefits include improving your child's time spent on task during instruction and increase his/her academic achievement.

*Voluntary Participation:* Your child will participate in all classroom activities during this research project. However, the decision to allow your child's grades and scores to be used in recording and analyzing data for this project is completely voluntary.

*Confidentiality:* Your child's scores and grades will remain confidential to the extent allowed by law and University policy. To ensure confidentiality a code will be established by randomly assigning a number to each participant. All scores and grades for data analysis will be recorded using this code. The code as well as all data collected during the study will be stored in a secure place and will be accessible only to the researcher. Neither your child nor his/her scores or grades will be personally identified. The code will be destroyed at the conclusion of the study.

*Right to Withdraw:* If you choose to allow your child's scores to be used now, but at any time and for any reason change your mind, you may withdraw your consent. In that case your child's scores and grades would not be recorded in the project data. There would be no negative consequences for this decision.

*Informed Consent:* I, \_\_\_\_\_, have read the description of this study.  
(please print your name)

I understand the purpose of the project, the procedures to be used, the potential risks and benefits, how confidentiality will be established and maintained, as well as the option to withdraw. I have read and discussed this project with my child

\_\_\_\_\_  
(please print your child's name)

My signature below indicates that I and my child freely agree for his/her scores and grades to be recorded and analyzed as a participant in this project.

\_\_\_\_\_  
Parent/Guardian

\_\_\_\_\_  
Child/Participant

\_\_\_\_\_  
Date

**University of Arkansas**  
**Parent or Legal Guardian Permission for Child to Participate in a Research Study**  
**\*\*\*Title of Research Project\*\*\***

You are being asked to give permission for your child to participate in a research study. Before you give permission for your child to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what your child is being asked to do.

**Investigators**

My name is **\*\*your name\*\***. I am graduate student in the **\*\* Program or course of Study\*\*** University of Arkansas. My advisor is Dr. **\*\*Name and title of advisor\*\***.

**Purpose of the Research**

This research study is designed to find **\*\*research question\*\***.

The data from this research will be used to **\*\*what you are doing with the data\*\***.

**Procedures**

If you allow your child to participate in this study, he/she will be asked to complete a survey that will include **\*\*describe study\*\***. It will also include questions about **\*\*explanation of questions\*\***.

Your child's participation will take approximately **\*\*how long will it take and where the research will take place\*\***.

Your child will be asked to assent to participate in this research. He/she can refuse to participate without penalty or can stop participation at any time just by telling the investigator that he/she wants to stop.

**Potential Risks or Discomforts**

**\*\*Risks\*\***.

**Potential Benefits of the Research**

**\*\*Benefits\*\***.

**Confidentiality and Data Storage**

Your child's name will only be collected on this permission form and will not be connected to his/her survey in any way. In addition, your child's teacher and school district will be kept confidential to the extent allowed by law and University policy.

**\*\*Location of completed surveys and who will have access to them\*\***.

**Participation and Withdrawal**

Participation in this research study is voluntary. You may refuse to allow your child to participate without penalty to you or your child. If you decide to allow your child to participate, you are free to stop his/her participation without penalty by just telling the investigator. In addition, your child may stop participating by telling the investigator that he/she wants to stop.



**Title of Research Project**  
**Consent to Participate in a Research Study**  
Principal Researcher: Principal Researcher's Name  
Faculty Advisor: Faculty Advisor's Name

**INVITATION TO PARTICIPATE**

You are invited to participate in a research study about . You are being asked to participate in this study because you .

**WHAT YOU SHOULD KNOW ABOUT THE RESEARCH STUDY**

*Who is the Principal Researcher?*

Principal Researcher's name and contact information

*Who is the Faculty Advisor?*

Faculty Advisor's name and contact information

*What is the purpose of this research study?*

The purpose of this study is

*Who will participate in this study?*

Number of expected participants, who they are, age range, etc.

*What am I being asked to do?*

Your participation will require the following:

*What are the possible risks or discomforts?*

List any possible risks. It is permissible to say there are no anticipated risks to participating, if this is the case.

*What are the possible benefits of this study?*

This question asks for benefits to the participant, not just the knowledge gained by the study. It is permissible to say there are no anticipated benefits to the participant, if this is the case.

*How long will the study last?*

Make clear to your participant how long their participation will take, whether a 15-minute survey, or three one-hour meetings spread out over a month, etc.

*Will I receive compensation for my time and inconvenience if I choose to participate in this study?*

*Will I have to pay for anything?*

This will generally say, No, there will be no cost associated with your participation.

*What are the options if I do not want to be in the study?*

If you do not want to be in this study, you may refuse to participate. Also, you may refuse to participate at any time during the study. Your job, your grade, your relationship with the University, etc. will not be affected in any way if you refuse to participate.

*How will my confidentiality be protected?*

All information will be kept confidential to the extent allowed by law and University policy. Add whatever steps are being taken to ensure confidentiality, whether data will be anonymous, records will be locked in a secure area, etc.

By signing this consent form, you give permission for the Arkansas Department of Health, the Office of Human Subjects Protection, the UA IRB, and any other UA oversight offices to verify clinical trial procedures and/or data. No identifying information will be reported at any future presentation or published in any future publication.

*Will I know the results of the study?*

At the conclusion of the study you will have the right to request feedback about the results. You may contact the faculty advisor, Name and contact information or Principal Researcher, Name and contact information. You will receive a copy of this form for your files.

*What do I do if I have questions about the research study?*

You have the right to contact the Principal Researcher or Faculty Advisor as listed below for any concerns that you may have.

Principal Research's name and contact information

Faculty Advisor's name and contact information

You may also contact the University of Arkansas Research Integrity & Compliance office listed below if you have questions about your rights as a participant, or to discuss any concerns about, or problems with the research.

Ro Windwalker, CIP  
Institutional Review Board Coordinator  
Research Integrity & Compliance  
University of Arkansas  
105 MLKG Building  
Fayetteville, AR 72701-1201  
479-575-2208  
[irb@uark.edu](mailto:irb@uark.edu)

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I understand the purpose of the study as well as the potential benefits and risks that are involved. I understand that participation is voluntary. I understand that significant new findings developed during this research will be shared with the participant. I understand that no rights have been waived by signing the consent form. I have been given a copy of the consent form.

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TIPS ON INFORMED CONSENT

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The process of obtaining informed consent must comply with the requirements of **45 CFR 46.116**. The documentation of informed consent must comply with **45 CFR 46.117**. The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.
- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.
- **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[j]), an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.

- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.
- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations (45 CFR 46.116[a][8]).** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.
- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections 46.116(b), 46.205(a)(2), 46.207(b), 46.208(b), 46.209(d), 46.305(a)(5-6), 46.408(c), and 46.409(b). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

Revised 3/16/93

**§46.116 - Informed Consent Checklist - Basic Elements**

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

**IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent**

**§ 46.116** - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

<b>Both boxes of C must be checked, or all four boxes of D:</b>	
	<b>C: 1.</b> The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
	<b>C: 2.</b> The research could not practicably be carried out without the waiver or alteration.
<b>OR</b>	
	<b>D: 1.</b> The research involves no more than minimal risk to the subjects;
	<b>D: 2.</b> The waiver or alteration will not adversely affect the rights and welfare of the subjects;
	<b>D: 3.</b> The research could not practicably be carried out without the waiver or alteration; and
	<b>D: 4.</b> Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**§46.117 Documentation of Informed Consent Checklist**

a. Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b. Except as provided in paragraph (c) of this section, the consent form may be either of the following:

<b>WRITTEN</b>	1. A <b>written consent</b> document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
<b>DONE ORALLY</b>	2. A <b>short form written consent</b> document, stating that the elements of informed consent required by §46.116 have been presented <b>orally</b> to the subject or the subject's legally authorized representative. When this method is used, there shall be a <b>witness</b> to the oral presentation. Also, the IRB shall approve a <b>written summary</b> of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

<b>WAIVER of require. for signed form</b>	1. That the only record linking the subject and the research would be the consent document, and the <b>principal risk</b> would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or 2. That the research presents <b>no more than minimal risk</b> of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
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## **Exempt Categories**

**(Exempt studies can be reviewed administratively by the IRB Compliance Coordinator.)**

**Category 1:** Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This category should be limited to the study of normal educational practices, and should not include radically new instructional strategy or instructional methods, or research involving deception.

**Category 2:** ) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

This category should not include research using identifiable data that may cause psychological distress, or are considered sensitive such as sexual preferences, substance abuse, or illegal conduct.

Research involving survey or interview procedures in children are not exempt. Research involving observations of public behavior in children are not exempt unless the investigator(s) do not participate in the activities being observed.

**Category 3:** Research involving the use of educational tests

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers

linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

**Category 4:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot

be identified, directly or through identifiers linked to the subjects.

Existing data means that the data or specimens exist at the time the research study is submitted to the IRB. Research that involves the ongoing (i.e., prospective) collection of specimens and/or data is not exempt under this category.

Publicly available means information that is available to the general public, such as census data. If you have to submit a request for the data or sign a data use agreement, it is not publicly available.

Non-public data or specimens must be de-identified, and may not be linked to identifiers by a code available to the investigator(s). If the investigator(s) intend to retain or can access any identifiers, the research project is not exempt under this category.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

**Category 5:** Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

This category allows research on public benefit or service programs, such as welfare, Medicaid, unemployment and Social Security. However, research in these categories may involve vulnerable populations who require additional protections.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

**Category 6:** Taste and food quality evaluation and consumer acceptance studies if:

(i) wholesome foods without additives are consumed; or  
(ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research in this category should be limited to taste and food quality studies that do not involve a type or volume of food that could pose any risk to subjects. Studies that involve consumption of alcohol, vitamins, or supplements do not qualify for exempt status.

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).



(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101>

## **Expedited Categories**

**(Expeditable studies can be reviewed by a single IRB member and do not have to be reviewed at the full convened board meeting.)**

### **Applicability**

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

### **Research Categories**

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;  
or

(b) from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human

subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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<sup>1</sup> An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

<sup>2</sup> Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).

Source: 63 FR 60364-60367, November 9, 1998.