**Human Subject Regulations Decision Chart I**

The Office for Protection from Research Risks (OPRR) provides the following graphic aids to clarify portions of the Department of Health and Human Services (DHHS) human subject regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46). These portions of the regulations are the subjects of frequent inquiries to OPRR.

Definition of Human Subject at Section 46.102(f)

Is the definition of “human subject” at Section 46.102(f) met in this research activity?

Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion, but for this research?

Yes

No

Will identifiable private data/information be obtained for this research in a form associable1 with the individual?

45 CFR Part 46 does not apply.

Yes

Human subjects involved.

Follow 45 CFR 46 or meet criteria for exemptions (See Chart 2).

1That is, the identity of the subject is, or may readily be, ascertained or associated with information.

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**Human Subject Regulations Decision Chart 2**

**Exemption at Section 46.101(b)(4)**

This exemption regards research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

**Is the research exempt in accordance with Section 46.101(b)(4)?**

The regulations at 45 CFR Part 46 do not apply if the criteria for exemption under Section 46.101(b)(4) are met.

Will this research use solely existing1 data or specimens?

No

Yes

Are those data or specimens publicly available?

No

Yes

Will information be recorded by the investigator in such a way that it can be linked to the subject?

No

Yes

This research is exempt from 45 CFR Part 46.

This exemption does not apply. This research may be eligible for IRB waiver of informed consent (Section 46.116(d)). See Chart 3.

1”Existing” means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and nonresearch activities.

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**Human Subject Regulations Decision Chart 3**

**Waiver or Alteration of Informed Consent under Section 46.116(d).**

**Can the Institutional Review Board employ Section 46.116(d) to waive informed consent or alter informed consent elements?**

1. Will the research in its entirety involve greater than “minimal risk” (Section 46.102((i))?

Yes

No

No waiver or alteration

2. Is it practicable to conduct the research without the waiver/alteration?

Yes

No

No waiver or alteration

3. Will waiving/altering informed consent adversely affect subjects’ rights and welfare?

Yes

No

No waiver or alteration

4. Will pertinent information be provided to subjects later, if appropriate?

No

Yes

Waiver or alteration possible, if IRB documents these 4 findings and approves the waiver or alteration.

No waiver or alteration

OPRR February, 1998

**Mount Wachusett Community College**

RESEARCH INVOLVING HUMAN SUBJECTS

**INFORMED CONSENT**

Title of Project:

Researcher:

Invitation to Participate: You are invited to participate in this research study. The following information is being provided to help you make an informed decision on whether to participate. If you have any questions, do not hesitate to ask.

Purpose: What we hope to learn *(to be filled in by researcher). If this research is supported by a grant, name the grant.*

Subjects: *Researcher should state why the subject* *is eligible to participate*.

Procedures: If you should decide to participate we will (*in language understandable to your population, describe the procedures to be followed, including their purpose, duration, frequency, and any other pertinent information. If audio/videotaping or filming is a part of the procedures, insert a statement permitting the subject to review and/or edit the recording. Define how they will be used, for what purpose, and the disposition of the material at the end of the study).*

Alternatives: *If applicable, describe what alternative procedures or treatments may be available to the subject. If the study only involves an interview or questionnaire, this section is not applicable.*

Timetable: *Identify the length of time that will be required of the subject and the length of time that will be needed to complete the study.*

Risks: *Present a fairly detailed explanation of the risks involved to the subject. If there are no known risks, including discomfort, burden, or inconvenience, this should be stated.*

Benefits: *Clearly state the benefits of participating in the study. If there is no direct benefit to the subject, this should be stated in explicit terms. Also describe potential societal benefits in this section.*

Compensation: *Any compensation to the subject should be clearly stated. If a cash payment is involved, the amount should be stated in dollar terms. Any other conditions for compensation such as partial payment, no payment for early termination in the research, or bonuses for participation should be stated. If compensation is in the form of academic credit, the amount and type of credit should be clearly stated as well as any conditions that must be fulfilled in order for the credit to be awarded. The nature, amount, and method of payment of compensation must not constitute undue inducement of the subject. When establishing the amount or type of compensation, the researcher should consider the background and socioeconomic status of the subject population. Compensation of minor children involved in research is generally discouraged.*

In Case of Emergency Contact Procedure/Emergency Care and Compensation in Case of Injury: *Only applicable to subjects who are participating in a project that involves greater than minimal risk.*

Confidentiality: Any information obtained during this study which could identify you will be kept strictly confidential. This information may be published in professional, scientific journals in print or in electronic format, or be presented at professional meetings. *State the way in which the subject’s confidentiality will be maintained. State the persons or agencies who will have access to the information gathered from the study, the nature of information to be furnished, and the purpose of the disclosure.*

Right to Refuse or Withdraw: You may refuse to participate in the study or you may change your mind about being in the study and quit after it has begun without suffering any penalty after withdrawing.

Questions: If you have any questions about the research study, you may ask them now; or if you have questions later, you may ask (*name of principal researcher and telephone extension or email address).*

You have the right to ask for a signed and dated copy of this form.

In signing the form below in the space provided, you are indicating that you have voluntarily decided to participate in this research project as a subject and that you have read and understand the information provided above.

Subject’s signature Date

Printed name

To the best of my knowledge, the subject certifies that the subject voluntarily signed this form giving informed consent to participate in this research study.

Researcher’s signature Date

Researcher’s printed name and title