revised Common Rule

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revised Common Rule

Implementation 1/21/19
The Current Common Rule has not been revised since its publication in 1991

• After delays the revisions to the Common Rule will be in effect on 1/21/19

• The Common Rule is defined as a regulation governing the use of human subjects in federal research. Institutions receiving federal research funding must follow the revised Common Rule.

  – **Purpose** of the revisions to the Common Rule:

    1. Strengthen protections for study participants
    2. Decrease administrative workload for researchers
Summary of the revised Common Rule

The U.S. Department of Health and Human Services and 15 other federal agencies issued a final rule to update regulations that safeguard individuals who participate in research. Most provisions in the new rule will go into effect in 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today’s dynamic research environment.
Summary of the revised Common Rule

The current regulations, which have been in place since 1991, are often referred to as the “Common Rule.” They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.
Summary of the revised Common Rule

In September 2015, HHS and the other Common Rule agencies published a Notice of Proposed Rulemaking (NPRM), which drew more than 2,100 comments. In response to concerns raised during the extensive review process, the final rule contains a number of significant changes from the proposed rule, including the removal of a provision that would have required researchers to obtain consent before using a study participant’s non-identified biospecimens. The final rule maintains the current practice with respect to oversight of these specimens.
**OHRP definition of research**

*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
First Change of the revised Common Rule

“Over the years, many have argued that consent forms have become these incredibly lengthy and complex documents that are designed to protect institutions from lawsuits, rather than providing potential research subjects with the information they need in order to make an informed choice about whether to participate in a research study,” said Jerry Menikoff, MD, who directs the HHS Office for Human Research Protections, which led the government’s efforts to overhaul the regulations. “We are very hopeful that these changes and all the others that reduce unnecessary administrative burdens will be beneficial to both researchers and research participants.”
First Change of the revised Common Rule

Consent:
Consent-The requirement for consent forms to provide potential research subjects with a better understanding of a project’s scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.

- The consent document for greater than minimal risk will have a summary table on the first page of the consent
Concise Summary (maximum of one page)

This is a voluntary research study to find out (summarize what is being studied, describe the research treatment (randomization, blinding, observational) and follow-up (number of visits, length of time in the study, etc.), participant responsibilities (i.e., lifestyle changes, medication diaries, questionnaires, etc.). You do not have to take part to receive treatment and you may quit at any time.
There are risks to this study *drug/device/procedure* that are described in this document. Some of the more common and/or serious risks include: *do not cut and paste the risks section!* *Focus on a few of the common and a few of the serious risks.*

The potential benefit may be *(describe the potential benefit such as less pain, slowing the progression of your disease, etc.)*; however, there may be no direct benefit to you from taking part in this study. If you do not take part, or you withdraw from the study, you may receive the standard treatment *(describe the standard of care treatment for this condition).*

If you are interested in learning more about this study, please continue reading below.
Second Change of the revised Common Rule

Single IRB

Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies. The proposal from the NPRM has been modified, however, to add substantial increased flexibility in now allowing broad groups of studies (instead of just specific studies) to be removed from this requirement.

This is a requirement for NIH funded studies

Single IRB (sIRB) can be executed in a variety of ways:

1. SMART IRB or IRBx
2. External IRB’s such as WIRB or Chesapeake
3. Other
The IRB application now can accommodate for the other external IRB’s and international research:

4.3 If an external IRB is being requested select which IRB below:


- Advanta (Schulman + Chesapeake)
- WIRB - Western Institutional Review Board
- NCI CIRB - National Cancer Institute Central Institutional Review Board
- Quorum Institutional Review Board
- IREx - (IRB Reliance Exchange/SMART IRB)
- Other

If selecting Other or IREx - (IRB Reliance Exchange/SMART IRB) complete the table below

<table>
<thead>
<tr>
<th>IRB of records name</th>
<th>IRB contact name</th>
<th>Email or phone # of the contact person</th>
<th>IRB of records FWA#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke</td>
<td>Susie</td>
<td>123-123-1234</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>222222</td>
</tr>
</tbody>
</table>

Is this International Research? [ ] Yes  [ ] No

If Yes, complete the table below providing information specific to the country where research is taking place: *List the US IRB information in question above*

<table>
<thead>
<tr>
<th>IRB of records name</th>
<th>IRB contact name</th>
<th>Email or phone # of the contact person</th>
<th>IRB of records FWA# (enter N/A if the facility does NOT have an FWA)</th>
</tr>
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</table>
Commercial break
EXEMPT RESEARCH:
The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules.

1. 8 Exempt categories (6) will be implemented at Beaumont. Exempt categories 7 and 8 are applying broad consent and are not applicable for Beaumont.

2. IRB application has the 6 Exempt categories
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 1: (small modification)

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.
EXEMPT RESEARCH Category 2: (modified)

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 participants cannot readily be ascertained, directly or through identifiers linked to the participants;
EXEMPT RESEARCH Category 2 (cont.):

(ii) Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
Third Change of the revised Common Rule

**EXEMPT RESEARCH IRB application questions:**

**Exempt Category 2:** Will this research *only* include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)? If yes, more questions will pop up:

Will the information obtained be 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? *Yes or No question will pick up the difference between (i or iii)*

Would any disclosure of the human subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation?
**Third Change of the revised Common Rule**

**EXEMPT RESEARCH Category 2 examples:**

- A researcher interacts with students during a science class providing instructions and recording the audio activity of the students questions and comments. There are no risk of adverse reaction to the educator or students. Identity will be possible.

- A researcher interacts with students during a science class providing instructions and recording the audio activity of the students questions and comments. There are no risk of adverse reaction to the educator or students. No Identity of the students will occur in the group setting.
EXEMPT RESEARCH Category 3: (NEW)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant 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 the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 3:

(B) Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
EXEMPT RESEARCH Category 3:

(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 participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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 participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
EXEMPT RESEARCH Category 3 IRB application questions:

Exempt Category 3: Does this study include only 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 with the subject’s prospective agreement to the intervention and information collection?

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.

Will the research include children (i.e., participants under the age of 18)? Children are not permitted to be included per the federal regulations. If Children are included the answer should be NO and use the expedited criteria. Yes will be a hard stop and you will be forced to answer the expedited questions on the IRB application. Be careful on the hidden questions. *Change the hidden questions first before you change the main question.
EXEMPT RESEARCH Category 3 IRB application questions:
Will the information obtained be 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? The IRB will look to compare the PHI questions.
Will any disclosure of the human subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation? If Yes this will have to be justified and may require a change in the IRB application.
Will the research involve deceiving the subjects regarding the nature or purposes of the research? Permitted, but you will have to explain how you will let participants know there is a general research activity.
Commercial break
EXEMPT RESEARCH Category 4: (modified)
Secondary research (re-using identifiable information and identifiable biospecimens that are collected for some other ‘primary’ or ‘initial’ activity) 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 participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants. If a researcher would like to re-identify participants using their biospecimens, the research must be reviewed under the expedited categories for research.
EXEMPT RESEARCH Category 4:

(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 non-research 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.
EXEMPT RESEARCH Category 4 IRB application questions:

1. Does this study involve Secondary research for which consent is not required?

*Secondary research is defined as using identifiable private information or identifiable biospecimens originally obtained (prospectively or retrospectively) for non-research purposes or for research other than the current proposal.*

• Big change to allow prospective data
• HIPAA requires if you are *reasonably* able to obtain consent of the prospective collection you should do so.

Important to provide proper justification for your Waiver if consent is not possible.
EXEMPT RESEARCH Category 4 IRB application questions:

2. Are the identifiable private information or identifiable biospecimens publicly available?

3. Will the Information, which may include information about biospecimens, be 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?

4. Does the research involve only information collection and analysis involving the investigator’s use of identifiable health information when the information was originally collected for “health care operations”, “research” or “public health activities and purposes” as those terms are defined in the HIPAA regulations?
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 4 IRB application questions:
5. Is the research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology 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.?
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 4 examples:

1. Chart review study pulling identifiers for all patients who have had a chest CT from 1/1/16-12/31/19 to evaluate the incidental findings present on the CT of the chest. (retrospective and prospective chart review with identifiers)

2. Chart review study pulling identifiers for all patients who have had a breast biopsy from 1/1/16-12/31/19. The researcher will pull data and biospecimens results to evaluate the participants ER/PR status and Her2 status. (retrospective and prospective chart review with identifiers)
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 4 examples:
Chart review study pulling identifiers for all patients who have had a breast biopsy from 1/1/16-12/31/19. The researcher will pull data and biospecimens to evaluate the participants ER/PR status and Her2 status.

*If a researcher wants to now re-contact or perform additional biospecimens collection on the participants the research will not be permitted to be exempt research. The study will move to the expedited research category.

*Biospecimens was the most debated topic in the comments prior to the revised Common Rule NPRM
EXEMPT RESEARCH Category 5: (modified)

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.
EXEMPT RESEARCH Category 5: (cont)

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.
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 5:

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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 participants.
EXEMPT RESEARCH Category 5 IRB application questions:

Is this study a research and demonstration project 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 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. **Yes No**
EXEMPT RESEARCH Category 5 examples:

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. This is a rare category used at Beaumont, but may include an agency coming to Beaumont and reviewing our infection rates on a particular matter. An example could be the CDC would like to evaluate the occurrence of herpes at Beaumont neonates born between October 1, 2016-December 32, 2018.
Third Change of the revised Common Rule

EXEMPT RESEARCH Category 6: (no changes)

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.
EXEMPT RESEARCH Category 6 IRB application questions:

Does the study involve 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. Yes No
EXEMPT RESEARCH Category 6 example:
A researcher would like to perform taste evaluations between 5 protein bars. 5 samples are set before a participant and they eat all 5 samples of the protein bar. The participants name and contact information can be saved and the participant can state their preference and why they preferred one protein bar over another.
Commercial break
Fourth Change of the revised Common Rule

Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.

1. Exempt research
2. Expedited research
3. Greater than minimal risk research with no research activity i.e. follow up for survival
4. Greater than minimal risk studies with research activities will continue to require a full Progress Report
**Fourth Change of the revised Common Rule**

Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.

This means if you are continuing your research you will send in an **Annual Administrative Check In** for Research Administration through the IRB-iMedRIS.

- COID and CITI remains a required step for your ongoing research
- The Annual Administrative Check-In has very brief questions
  1. Enrollment status
  2. Breach of confidentiality
  3. Unresolved complaints
  4. Any noncompliance of the researchers
Fourth Change to the revised Common Rule Progress Report/Annual Administrative Check-In

1. The form has to be built if you have the current form you will answer more questions but the process will be no expiration on your consent or information sheets and the annual check in will an administrative action not the IRB action 😊

2. The form will branch and you will say there is ongoing greater than minimal risk research activity or all research activity is completed. All other research will branch to the Annual Administrative Check-In
Fourth Change to the revised Common Rule
Progress Report/Annual Administrative Check-In

3. Existing studies will be converted over to the revised Common Rule as studies are due for continuing renewal.
4. If the study was previously determined to be Exempt you will receive an email through iMedRIS study correspondence asking for the status of the study. If the study is going to continue the study will have a new annual renewal from the date of the email correspondence. Pay attention to your iMedRIS correspondence.
5. Your notification of sending in the Progress Report for an expedited study will allow you to flip to the revised Common Rule 2018 effective 1/21/19
Fourth Change to the revised Common Rule Progress Report/Annual Administrative Check-In

6. Exempt and Expedited studies with either a consent or Information Sheet will not require an expiration date on the document. The only time the IRB will re-stamp the document is if there is a change to the consent or Information Sheet. This mean a study approved on 1/21/19 and has a consent the stamp will stay as approved on 1/21/19 and remain even with an annual administrative check in future years, i.e. 2020.
Fifth Change of the revised Common Rule

Consent forms for Federally funded studies and working with a central IRB:

Requirement the consent forms for certain federally funded clinical trials to be posted on a public website.

1. Who will post the consent?
2. What consent template will be used?
3. Who makes the consent available in the Beaumont template with the Beaumont header and HIPAA?
4. Where will the consents be posted? Clinicaltrials.gov
5. Discussion is evolving with SMART IRB and IRBx tomorrow on how this will be done.
Change of the revised Common Rule

Global comments

There are hidden questions to the IRB application. When you answer “Yes” to a question more questions may unfold.

- Social security number answer “No” the form will continue to the next element of PHI
- Social security number answer “Yes” the form will expand to the hidden question:
  - Provide the rationale for collecting social security numbers:
Change of the revised Common Rule

Global comments
Example of hidden questions to the IRB application. **Exempt Category 3:** Does this study include only 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 with the subject’s prospective agreement to the intervention and information collection? **“No”** the additional questions stay hidden. If you answer **“Yes”** questions will appear.
Will the research include children (i.e., participants under the age of 18)?
*WARNING*-If you change the answer to the top question the folded/hidden questions need to be changed first.
Thank you for your contribution to research. Without your hard work, medical practice would not advance. Each and everyone of you are an important part of the process!

Medical advances would not be possible without individuals who volunteer to participate in research. Oversight and protection of research participants is an important safeguard and essential to advancing the research enterprise. Today’s action reaffirms the federal government’s commitment to all those who participate in research studies.
Work sessions are planned for researchers to sit at a work station (computer) and ask questions.

IRB assistance session handouts are available in the back and there will be broadcast messages sent out regarding the hands on work sessions.

QUESTIONS
Embed a video file that is stored on your computer

1. Open the slide you want to add video to.
2. Click the 'Insert' tab.
3. Click the 'Video' button in the 'Media' section.
4. Select 'Video on My PC'.
5. Find the video you want to add.
6. Wait while the video is added to your presentation.
7. Click the 'Playback' tab to adjust playback settings for the video.
8. Use the 'Start' drop-down to select how the video will start playing.
9. Resize the video by dragging the corners.
10. Save your presentation with the embedded video.

You won't need to send the video along with the presentation, since it's packed into the presentation itself. This means the presentation file size will increase to include the full video file.

Embed a YouTube video into your PowerPoint presentation

1. Using your web browser, open the YouTube video that you want to embed.
2. Click the 'Share' button, then click the 'Embed' tab.
3. Copy the highlighted embed code.
4. Open the slide in PowerPoint that you want to embed the video into.
5. Click the 'Insert' tab in PowerPoint.
6. Click the 'Video' button and select 'Online Video' or 'Video from Web Site' (depending on your PowerPoint version).
7. Click the 'Paste embed code here' box and paste the copied code. In PowerPoint 2010, the box will be labeled 'Insert Video From Website'.
8. Embed the video. The video will appear on the slide, most likely as a solid black box.
9. Click the 'Playback' tab to adjust playback options for the video.
10. Click the 'Start' drop-down menu and select how the video will play. If you do not select one the options from this menu, your video will not play during the presentation.

The YouTube video will only play if you are connected to the internet while you are giving your presentation. It will not play if you are offline.