OFFICE OF ADOLESCENT HEALTH

TEEN PREGNANCY PREVENTION PROGRAM

MEDICAL ACCURACY REVIEW GUIDANCE

October 2015

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PART ONE: INTRODUCTION

This guidance describes the medical accuracy review (MAR) process used by the Office of Adolescent Health (OAH) for the Teen Pregnancy Prevention (TPP) program. OAH implements a systematic process initiated to help ensure program materials proposed for use in OAH TPP grant projects are medically accurate. TPP grant programs administered by OAH are required to provide medically accurate, complete and age appropriate information. OAH's mandate for medical accuracy is based on statutory language contained in the Fiscal Year 2010 appropriations bill, which first authorized the TPP program, as well as in annual appropriations bills thereafter.[1] To ensure that the most current science is reflected in the program materials, TPP grantees must comply with having program materials reviewed by OAH prior to program implementation; this requirement is a condition attached to the Grantee Notice of Grant Award.

The definition of medical accuracy used by OAH was adopted from the Patient Protection and Affordable Care Act and reads as follows:

> The term *medically accurate and complete* means verified or supported by the weight of research conducted in compliance with accepted scientific methods; and published in peer-reviewed journals, where applicable or comprising information that leading professional organizations and agencies with relevant expertise in the field recognize as accurate, objective, and complete.[2]

The OAH Funding Opportunity Announcements (FOAs) specify that if approved for funding, all program materials must be submitted for MAR before implementation to ensure information provided to program participants is medically accurate. In addition, as described in the FOAs grantees are asked to conduct an internal medical accuracy review before submitting their program materials to OAH. [3-6]

The grantee internal review and the OAH review of program materials for medical accuracy occurs during the planning phase of the first grant year. All funded grantees must have program materials reviewed and any required modifications in place prior to use in the project. This guidance provides an overview of the process OAH uses to ensure information presented in OAH TPP projects is medically accurate.

After the grantee conducts a thorough needs assessment and selects a program to implement, the medical accuracy review process begins. Step one is for the grantee to review the program materials proposed for use in the OAH project, referred to in this document as the grantee internal review. After the grantee finalizes their internal review and addresses any issues found, step two begins with the submission of the materials to OAH. After the OAH review there are two possible outcomes: (1) no medical accuracy issues are identified and the program materials are ready for implementation in the project, or (2) medical accuracy issues are identified and modifications are required before program implementation can begin. If modifications are required, the grantee must address the medical accuracy issues and resubmit their response to OAH for further review. Step three is the grantee receiving written notice from OAH that they can move forward with implementation of the program materials in the project.

PART TWO: MATERIALS THAT REQUIRE MEDICAL ACCURACY REVIEW

All program materials, whatever the medium, must be reviewed for medical accuracy, including materials that do not contain medical information (e.g., positive youth development). Program materials used in control groups must also be submitted for review. Examples of program materials that require review include: teacher and student manuals, curricula, videos, pamphlets, handouts, classroom activities, slide presentations, interactive media, and internet materials that are part of the program. Medical topics addressed commonly in program materials include contraception and sexually transmitted infections (STIs), including the human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). Reproductive anatomy and pregnancy are also often addressed in program materials.

PART THREE: REVIEW PROCESS

Grantee Internal Review

After selecting program materials for the OAH project the grantee is expected to review their materials internally for medical accuracy by either program staff or an independent contractor. OAH provides grantees with a variety of tools to assist the grantee or their designee with their MAR[7]. Tools include a list of frequently used resources by topic area, the OAH MAR report template, a webinar on the OAH MAR process (recording, transcript and slides), a series of frequently asked questions (FAQs), reviewer tip sheet, template for tracking materials, and a timeline for the MAR process

If the grantee-led review finds medical accuracy issues, grantees should make appropriate updates or modifications prior to submitting their materials to OAH for the medical accuracy review. For assurance that plans to correct medically inaccurate information are not perceived as copyright infringement, OAH recommends that grantees contact the

copyright holder for written permission prior to making any alterations to curriculum materials. In addition, grantees should be aware that reproducing program materials and/or making modifications to these materials may result in copyright infringement. Thus, OAH is not expecting that grantees reproduce or make such modifications to these materials without first obtaining written permission from the copyright holder. If appropriate, a grantee may also wish to consult an attorney for guidance on copyright issues.

There are two ways to address modifications that are unlikely to raise copyright concerns, depending on if the materials are copyrighted by a third party or are owned by the grantee.

> *For copyrighted materials requiring modifications*: An insert page can be developed to detail all issues and modifications. The insert page should include the page numbers, paragraph numbers, inaccurate information that needs to be addressed, and replacement information. This insert page should be submitted to OAH along with program materials.

> *For materials requiring modification that are owned by the grantee, or for copyrighted materials where the grantee has permission from the copyright holder:* Modifications can be made directly to the program materials to address medical accuracy issues. An updated version of the program materials should be submitted to OAH for MAR.

When the grantee has identified all program materials planned for use in their OAH project and the grantee internal review is complete, the materials, with any modifications, need to be submitted to OAH for the MAR.

OAH Medical Accuracy Review

To help ensure the most current science is reflected in TPP program materials OAH uses the services of a contractor who works closely with OAH throughout the MAR process. OAH grantee program materials are sent to the MAR contractor. The contractor retains a team of consultants with expertise in adolescent health, teen pregnancy prevention, reproductive health, and other relevant areas. The contractor trains the medical experts on using the OAH MAR review form (Exhibit A), and provides guidance, training, resources, and references to assist with verifying information and substantiating recommendations.

Program materials submitted from OAH grantees undergo two independent reviews. The reviewers use the review form to document issues found, as well as recommend changes and provide references which support the recommendations. The review form includes a general description of the materials reviewed, a list of the medical topics addressed, a list of the medical accuracy issues identified, a recommendation for how to correct each identified issue, and any general comments for consideration, if necessary.

The two independent reports are reviewed and synthesized into a consolidated report. Both independent reports plus the consolidated report are sent to OAH for review. If there are questions before the consolidated report is sent to the grantee, the reviewers are contacted for any clarifications. Grantees are provided a copy of the consolidated report along with a letter from their OAH Project Officer informing the grantee if they can (1) proceed with implementation (Exhibit B), or if they are (2) required to make modifications to the materials (Exhibit C).

The grantees also receive a letter from the Director of OAH, which discusses copyright implications associated with grantee use and/or modification of the materials (Exhibit D). Grantees are notified that the U.S. Department of Health and Human Services (HHS) respects the rights of copyright owners. Under copyright law, copyright owners have exclusive rights to reproduce, distribute, and modify their works. Nothing in the report, the TPP Funding Opportunity Announcements, or the standard terms and requirements attached to the Grantee Notice of Grant Award implies that the government authorizes and consents to infringement of copyright in any work protected under the copyright laws of the United States.

A courtesy copy of the consolidated report is also shared with the program developer and/or purveyor so that they are made aware of any issues identified. Accompanying the consolidated report is a letter to the developer/purveyor from the Director of OAH which provides an explanation of the review process and the definition of medical accuracy (Exhibit E).

Developers/purveyors are advised that a curriculum should neither be characterized as approved by OAH nor contain any language indicating that all medical accuracy recommendations have been incorporated into the curriculum. HHS policy prohibits giving preferential treatment to any non-Federal entity, and therefore entities may not include statements in their materials that may be perceived to be endorsements by HHS.

If materials need modifications, grantees are required to submit to their OAH project officer plans for addressing the results of the MAR within 30 days of receiving the report. OAH reviews the modifications and notifies each grantee if the changes are acceptable. If the grantee has questions or needs clarification, OAH and the MAR contractor are available for review and discussion of any parts of the report with the grantee and the developer or purveyor.

Prior to using the program materials, the grantee must provide documentation to OAH showing that all modifications were made to address the medical accuracy issues noted in the MAR. The grantee will receive written notice from OAH that they may move forward with program implementation.

PART FOUR: EXAMPLES OF MEDICAL ACCURACY ISSUES

Examples of commonly identified medical accuracy issues include needing to add new information or make updates as new information becomes available. Updates may include new vaccine schedules for immunizations and information on new contraceptives that have been added to the marketplace. Medical accuracy issues can also come from incomplete language that requires updating. For example, when discussing the role of condoms in STI and HIV prevention, it should be specified that latex condoms, (or polyurethane, if allergic to latex) decrease the risk of STI/HIV transmission.[8] Natural membrane condoms are not recommended for the prevention of STIs and HIV. Grantees should also provide information or discuss that condom effectiveness varies with the different types of STIs.[9]

Materials need to emphasize that the use of a latex (or polyurethane) condom plus a reliable form of birth control (dual method) is a more effective approach to pregnancy and STI prevention than the use of one method alone.[10, 11, 12] In addition, abstinence should be defined as abstaining from oral, anal, and vaginal sex, and discussed as the most reliable way to prevent pregnancy and STI/HIV infection.[13]

The following guidelines provide information that should be covered when discussing STIs and birth control:

A. Sexually Transmitted Infections (STIs):

STI information should address the following infections and diseases in order for materials to be considered complete: Syphilis, gonorrhea, chlamydia, herpes simplex II, hepatitis B, human papillomavirus (HPV), trichomoniasis, and HIV/AIDS (i.e., CDC STD Fact Sheets[14, 15, 16]).

The information should include the following:

1. Type of organism that causes the STI (virus/bacteria/parasite),
2. Modes of transmission,
3. Symptoms,
4. Treatment,
5. Possible complications/sequelae, and
6. Prevention details.

If an immunization exists for a given STI, such as HPV and hepatitis B, this information also should be included. In addition, a recommendation of HIV and STI testing for sexually active individuals is critical.

B. Birth Control Information

Birth control information should describe each method, including the following:

1. How the method works
2. Duration of contraceptive effects
3. Effectiveness/failure rates (typical and perfect use)
4. Whether the method provides no protection from or reduces the risk of HIV/AIDS and other STIs
5. Health risks/drawbacks (medical/personal)
6. Benefits (medical/personal) associated with the method.

If a program includes information on STIs and contraception, the information included must be complete. However, if the program does not include information on STIs or contraception, it is not necessary for a grantee to add information on STIs or contraception to be considered medically accurate (e.g., Positive Youth Development programs).

When STI/STD and/or contraception education are part of a program, and the information is not complete, the grantee can provide links to reliable sources from the OAH resource list. The resource list (Exhibit F) is maintained on the OAH website and is updated periodically.[7] The resource list contains numerous references on various medical topics that are often discussed in TPP program materials. The resource list is used during reviews and is also available for grantees and other interested parties to help ensure current and accurate information. When medical accuracy issues are identified in program materials, links to resources such as the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Office of Population Affairs (OPA) are provided in the report to help grantees update their materials and ensure they remain current.

PART FIVE: SUMMARY

Medical accuracy is a vital component of any public health education program. OAH recognizes this and has a system in place to help grantees ensure their TPP program materials are medically accurate. Medical information is constantly evolving and as new discoveries are made, program materials can become outdated. Credibility is closely tied to accuracy, and programs that wish to impact and influence behaviors must ensure that information presented is medically accurate. Adolescents, along with all recipients of public health information deserve reliable, accurate information to best equip them to make healthy decisions for their lives. Medical accuracy reviews help ensure this occurs.

PART SIX: REFERENCES

U.S. Government Printing Office. PUBLIC LAW 111 -117 –DEC. 16, 2009.
Consolidated Appropriations Act, 2010. Available at:
http://www.gpo.gov/fdsys/pkg/PLAW-111publ117/pdf/PLAW-111publ117.pdf
Accessed July 1, 2015. (Identical language regarding medical accuracy has been carried
forward each year in annual appropriations bills.)

U.S. Government Printing Office. PUBLIC LAW 111 -148 –MAR. 23, 2010.
Patient Protection and Affordable Care Act. Available at:
http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf
Accessed July 1, 2015.

Department of Health and Human Services, Office of Adolescent Health. Funding
Opportunity Announcement (2015) for Capacity Building to Support Replication of
Evidence-Based TPP Programs (Tier 1 A). Available at:
http://www.hhs.gov/ash/oah/grants/2015%20FOAs/tier1a-foafile.pdf
Accessed September 28, 2015.

Department of Health and Human Services, Office of Adolescent Health. Funding
Opportunity Announcement (2015) for Replicating Evidence-Based Teen Pregnancy
Prevention Programs to Scale in Communities with the Greatest Need (Tier 1B).
Available at:
http://www.hhs.gov/ash/oah/grants/2015%20FOAs/tier1b-foafile.pdf
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Department of Health and Human Services, Office of Adolescent Health. Funding
Opportunity Announcement (2015) for Supporting and Enabling Early Innovation to
Advance Adolescent Health and Prevent Teen Pregnancy (Tier 2A).
http://www.hhs.gov/ash/oah/grants/2015%20FOAs/tier2a-foafile.pdf
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Department of Health and Human Services, Office of Adolescent Health. Funding
Opportunity Announcement (2015) for Rigorous Evaluation of New or Innovative
Approaches to Prevent Teen Pregnancy (Tier 2B). Available at:
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Accessed September 28, 2015.

Department of Health and Human Services, Office of Adolescent Health. Ensuring
Medical Accuracy of Teen Pregnancy Prevention (TPP) Programs: Grantee Webinar.
http://www.hhs.gov/ash/oah/resources-and-publications/webinars.html
Accessed September 28, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
2015 STDs Treatment Guidelines: Clinical Prevention Guidance.

http://www.cdc.gov/std/tg2015/clinical.htm
Accessed September 28, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
Condoms and STDs: Fact Sheet for Public Health Personnel.
http://www.cdc.gov/condomeffectiveness/latex.html
Accessed July 1, 2015.

Hatcher RA, Trussell J, Nelson AL, et al. Contraceptive Technology, Twentieth Revised
Edition. Atlanta (GA): Ardent Media, Inc.; 2011.

Committee on Adolescence. Condom Use by Adolescents. Pediatrics, 2013; 132(5):973-
981. Available online at:
http://pediatrics.aappublications.org/content/early/2013/10/23/peds.2013-2821.full.pdf
Accessed July 1, 2015.

Healthy People 2020. Available at:
http://www.healthypeople.gov/2020/topics-objectives/topic/Adolescent-Health/objectives
Accessed July 1, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
Sexually Transmitted Diseases: Prevention.
http://www.cdc.gov/std/prevention/default.htm
Accessed July 1, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
Sexually Transmitted Diseases: CDC Fact Sheets.
http://www.cdc.gov/std/HealthComm/fact_sheets.htm
Accessed July 1, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
Hepatitis B Information. http://www.cdc.gov/hepatitis/hbv/index.htm
Accessed July 1, 2015.

Department of Health and Human Services, Centers for Disease Control and Prevention.
HIV/AIDS: Fact Sheets. http://www.cdc.gov/hiv/library/factsheets/index.html
Accessed July 1, 2015.

EXHIBIT A: OAH MEDICAL ACCURACY REVIEW REPORT FORM

Template: Medical Accuracy Review Form for Curricula and Educational Materials
Proposed for Use by Teen Pregnancy Prevention (TPP) Grantees

Materials Submission Date:

Review Completed Date:

Materials Submitted by (Contact Person):

Grantee Name:

Grant #:

OAH Project Officer Name:

Curriculum/Material Name:

Components:

For Use in:

___ TIER 1A (Capacity Building)

___ TIER 2A (Early Innovation)

___ TIER 1B (Replicating EBPs)

___ TIER 2B (Rigorous Evaluation)

Edition:

Author:

Publisher:

Copyright Date:

Target Audience (if specified):

No. of pages/minutes (total and per component):

Does it contain medical information:

___ YES

___ NO

REVIEWER RECOMMENDATION

After you have completed your review of the material, please check your recommendation for this curriculum/material:

___ Meets the definition of medical accuracy

___ Meets the definition of medical accuracy with modifications (Recommended

modifications described in the Medical Accuracy Issues section)

___ Does not meet the definition of medical accuracy

DEFINITION OF MEDICAL ACCURACY

Medically accurate and complete programs are verified or supported by the weight of research conducted in compliance with accepted scientific methods and published in peer-reviewed journals, where applicable; or comprising information that leading professional organizations and agencies with relevant expertise in the field recognized as accurate, objective, and complete.

BRIEF DESCRIPTION AND PURPOSE OF THE MATERIAL:

MEDICAL TOPICS ADDRESSED
___ Contraceptives

___ HIV/STI/STD Testing

___ Brand Names

___ HIV/STI/STD Treatment

___ Sexually Transmitted Infections (STIs)/ Sexually Transmitted Diseases (STDs)

___ Reproductive Anatomy

___ HIV/AIDS

___ Pregnancy

___ Other: _____

REVIEW FOR MEDICAL ACCURACY

All materials used in TPP programs must be medically accurate. Materials covering medical topics (e.g., STIs/STDs, including human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), contraception) may not contain any inaccurate, outdated, or confusing/misleading medical information.

If the material being reviewed does not meet the definition of medical accuracy, please cite in the Medical Accuracy Issues section, the curriculum element, page number(s), and location on page; or minute and key words if a video, of where the discrepancy occurs. Please note the medical topic being addressed, and how each statement does not meet this definition (inaccurate, outdated, or confusing/misleading). Please also indicate whether the statement should be deleted or modified. If modification is required, please provide recommendations for making the material medically accurate.

MEDICAL ACCURACY ISSUES

Text

Issue 1
- Page Number:
- Paragraph or Exhibit:
- Medical Topic(s):
- Medical Accuracy Issue:
- Recommendation:
- Reference:

Video

Issue 1
- Minute Number:
- Description of Scene:
- Medical Topic(s):
- Medical Accuracy Issue:
- Recommendation:
- Reference:

GENERAL COMMENTS

Please use this section to provide any general information on the curriculum as a whole that has not been addressed in previous sections and is pertinent to the review. If modification is required, please provide recommendations for aligning the materials with the definition of medical accuracy.

EXHIBIT B: LETTER FROM OAH #1

(TO GRANTEE – PROCEED WITH IMPLEMENTATION)

Dear Grantee:

We reviewed the materials you propose to use in your OAH Teenage Pregnancy Prevention (TPP) grant. This review process was described in the TPP Funding Opportunity Announcement and included in the additional standard terms and requirements attached to your Notice of Grant Award. As part of this process, grantees are required to submit all curricula and educational materials (DVD/CD/videos) proposed for development or use within the TPP project to OAH for review prior to use in the project. The review process is carried out to ensure that materials used in TPP projects are medically accurate, complete, and up-to-date.

Enclosed, please find a copy of the completed medical accuracy report. The report includes a general description of the materials reviewed, a list of the medical topics addressed in the materials, a list of the medical accuracy issues that were identified, a recommendation for how to correct each identified issue, and other general comments for your consideration. Internet resources identified as an essential or core part of the program materials were also reviewed for medical accuracy. However, it is your responsibility to ensure that materials included on any internet web site remain medically accurate.

Based on the review, you may proceed with implementation of your TPP program materials referenced in the attached email. OAH will send a courtesy letter to the program developers and/or purveyor informing them of the results of the medical review of their program materials. You should have notified the developer/purveyor of your program that materials used in OAH grants must be reviewed for medical accuracy, that any identified inaccuracies must be corrected prior to use in an OAH project, and that this medical accuracy review process is a condition of your grant award.

With respect to any possible copyright implications associated with your use and/or modification of these materials, please see the letter dated June 3, 2011 from Evelyn Kappeler (Subject "Guidance on Intellectual Property and Medical Accuracy"), attached hereto. Keep in mind that the Department of Health and Human Services (HHS) respects the rights of copyright owners. Under copyright law, copyright owners have exclusive rights to reproduce, distribute, and modify their works. Nothing in this letter, the enclosed report, the TPP Funding Opportunity Announcement, or the standard terms and requirements attached to your Notice of Grant Award implies that the Government authorizes and consents to infringement of copyright in any work protected under the copyright laws of the United States within the meaning of 28 U.S.C. § 1498(b).

If you have any questions about the TPP medial accuracy review process, please contact me at __contact #_____ or ___e-mail address___.

Sincerely,

Project Officer Name
Project Officer
Teen Pregnancy Prevention
Office of Adolescent Health

Attachments:
Medical Accuracy Review Report
Email from Evelyn Kappeler, dated June 3. 2011 (Subject "Guidance on Intellectual
Property and Medical Accuracy")

EXHIBIT C: LETTER FROM OAH #2
(TO GRANTEE – MODIFICATIONS REQUIRED)

Dear Grantee:

We reviewed the materials you propose to use in your OAH Teenage Pregnancy Prevention (TPP) grant. This review process was described in the TPP Funding Opportunity Announcement and included in the additional standard terms and requirements attached to your Notice of Grant Award. As part of this process, grantees are required to submit all curricula and educational materials (DVD/CD/videos) proposed for development or use within the TPP project to OAH for review prior to use in the project. The review process is carried out to ensure that materials used in TPP projects are medically accurate, complete, and up-to-date.

Enclosed, please find a copy of the completed medical accuracy report. The report includes a general description of the materials reviewed, a list of the medical topics addressed in the materials, a list of the medical accuracy issues that were identified, a recommendation for how to correct each identified issue, and other general comments for your consideration. Internet resources identified as an essential or core part of the program materials were also reviewed for medical accuracy. However, it is your responsibility to ensure that materials included on any internet web site remain medically accurate.

Based on the review, you may not proceed with implementation of your TPP program materials until all required modifications are made. OAH will be sending a courtesy letter to program developers and/or purveyor informing them of the results of the medical review of their program materials. You should have notified the developer of your program that materials used in OAH grants must be reviewed for medical accuracy, that any identified inaccuracies must be corrected prior to use in an OAH project, and that this medical accuracy review process is a condition of your grant award.

With respect to any possible copyright implications associated with your use and/or modification of these materials, please see the letter dated June 3, 2011 from Evelyn Kappeler (Subject "Guidance on Intellectual Property and Medical Accuracy"), attached hereto. Keep in mind that the Department of Health and Human Services (HHS) respects the rights of copyright owners. Under copyright law, copyright owners have exclusive rights to reproduce, distribute, and modify their works. Nothing in this letter, the enclosed report, the TPP Funding Opportunity Announcement, or the standard terms and requirements attached to your Notice of Grant Award implies that the Government authorizes and consents to infringement of copyright in any work protected under the copyright laws of the United States within the meaning of 28 U.S.C. § 1498(b).

Your program materials require modifications; you must therefore submit to your OAH Project Officer your plans for addressing the results of the medical accuracy review, including a copy of the proposed modifications within 30 days of receiving this report.

OAH will review the modifications and notify you in writing if the modifications sufficiently address the identified issues found in the medical accuracy review.

If you have any question about the TPP medical accuracy review process or about making the necessary modifications to the materials you propose to use in your project, please contact me at __contact #_____ or ____e-mail address___.

Sincerely,

Project Officer Name
Project Officer
Teen Pregnancy Prevention
Office of Adolescent Health

Attachments:
Medical Accuracy Review Report
Email from Evelyn Kappeler, dated June 3. 2011 (Subject "Guidance on Intellectual Property and Medical Accuracy")

EXHIBIT D: LETTER FROM OAH #3
(TO GRANTEE – COPYRIGHT IMPLICATIONS)

June 3, 2011

Dear Grantee:

I am writing this letter to provide you with some general information regarding the use of materials in your OAH Teenage Pregnancy Prevention (TPP) grant project, the medical accuracy requirement, and potential copyright issues. Specifically, because you will be using and/or modifying pre-exiting materials in your OAH projects, you should be aware that there could be copyright implications associated with your use of these materials.

As indicated in the TPP funding announcement, OAH grantees need to ensure that information provided in their programs is medically accurate. To ensure that the most current science is reflected in the program materials, grantees are required to submit all program materials to OAH for review prior to use in the project. The review shall ensure that the materials are medically accurate, complete, and up-to-date. In cases in which medical inaccuracies are identified, grantees are required to correct any medically inaccurate information prior to beginning full implementation of their programs.

However, it is important to note that OAH is not expecting you to alter the materials beyond correcting the medically inaccurate information; nor is OAH expecting you to make actual modifications to the pre-existing written program materials, as these types of changes (e.g., additions, deletions or revisions to the text or graphics) could possibly infringe rights owned by the copyright holder. On the other hand, there may be a number of ways in which you can make the necessary revisions to the materials that will not alter pre-existing materials and, therefore, are unlikely to raise copyright concerns, such as: developing an insert for facilitators and including the insert at the beginning of the materials, supplementing existing handouts and PowerPoint slides with updated information, stopping a video after a medically inaccurate statement to correct the statement, etc. For assurance that your plans to correct medically inaccurate information are not perceived as copyright infringement, OAH recommends that you contact the copyright holder for written permission prior to making any alterations to curriculum materials. In addition, you should be aware that reproducing program materials and/or making modifications to these materials may result in copyright infringement. Thus, OAH is not expecting that you reproduce or make such modifications to these materials without first obtaining written permission from the copyright holder. If appropriate, you may also wish to consult an attorney for guidance on copyright issues.

HHS respects the rights of copyright owners. Under copyright law, copyright owners have exclusive rights to reproduce, distribute, and modify their works. (See the U.S. Copyright Office website http://www.copyright.gov for information on copyright laws and answers to frequently asked questions about copyright.) Nothing in this letter, the TPP Funding Opportunity Announcement, or the additional standard terms and requirements attached to your Notice of Grant Award, implies that the Government

authorizes and consents to infringement of copyright in any work protected under the copyright laws of the United States within the meaning of 28 U.S.C. §1498(b).

As individual materials are submitted and reviewed for medical accuracy, you will be receiving a letter from OAH letting you know if the program materials can be used in your project or, if not, what modifications are required to be made prior to use. In cases in which modifications are required, the OAH medical accuracy review contractor will be available to guide you through the process.

Sincerely,

Evelyn Kappeler
Acting Director
Office of Adolescent Health

EXHIBIT E: LETTER FROM OAH #4
(COURTESY COPY FOR DEVELOPER/PURVEYER)

Date

Dear _(Name of developer)_ :

The Office of Adolescent Health (OAH) has completed the medical accuracy review of your program materials: __(Name of program materials)___.

Teen Pregnancy Prevention (TPP) grantees are required to submit to OAH for medical accuracy review, all program materials proposed for use in their TPP project. The review process, which was described in the TPP Funding Opportunity Announcement and included as a condition of TPP grant awards, was designed to ensure that materials used in TPP projects are medically accurate.   OAH grantees may have notified you that program materials used in OAH grant projects must be reviewed for medical accuracy, that any identified inaccuracies must be corrected prior to use in an OAH project, and that this medical accuracy review process is a condition of OAH grant awards. The definition for medically accurate can be found in the TPP Funding Opportunity Announcements (2015). The definition was adopted from the Patient Protection and Affordable Care Act and reads as follows:

> The term "medically accurate and complete" means verified or supported by the weight of research conducted in compliance with accepted scientific methods; and published in peer-reviewed journals, where applicable or comprising information that leading professional organizations and agencies with relevant expertise in the field recognize as accurate, objective, and complete.

OAH contracted with an outside company to implement and manage the curriculum review process. The Contractor and OAH have identified a team of experts in the fields of adolescent health, reproductive health, obstetrics and gynecology, pediatrics, and other related disciplines to review program materials for medical accuracy. All materials are thoroughly reviewed to ensure that the information is medically accurate. A report is created documenting instances in the materials where the information presented is medically inaccurate. The report includes, for each item, the location in the program material where an issue was identified, the medical topic being addressed, a description of the medical accuracy issue, a recommendation to correct the issue, and a supporting reference.

All grantees implementing your program materials will receive a copy of the medical accuracy review report that details the medical accuracy issues noted during the review. Upon receipt of the report, grantees will have 30 days to submit their plan for addressing any issues noted in the report to OAH.   Grantees are required to ensure that all information included in their TPP Program is medically accurate and must describe their plan for correcting the medically inaccurate information to their Federal project officer.

Please note that any modified program materials should neither be characterized as approved by OAH nor contain any language indicating that all medical accuracy recommendations have been incorporated into the curriculum. The Department of Health and Human Services policy prohibits giving preferential treatment to any non-Federal entity; entities may not include statements in their materials that may be perceived to be endorsements by HHS.

We are providing you with a courtesy copy of the results from the OAH medical accuracy review. If you have any questions regarding the medical review process or report, feel free to contact the Office of Adolescent Health at (240) 453-2846 or oah.gov@hhs.gov

Sincerely,

Evelyn Kappeler
Director, Office of Adolescent Health

Enclosure: Findings from Medical Accuracy Review

EXHIBIT F: RESOURCE LIST BY TOPIC

Office of Adolescent Health (OAH)
Medical Accuracy Review
Frequently Used Resources by Topic
Updated on 08/31/15

Disclaimer: This is a list of some, but not all, of the relevant resources available. OAH does not endorse any of the resources listed other than those developed by HHS.

This list of resources is available to assist reviewers in verifying medical information or making recommendations for grantees regarding the medical information in their program materials. Suggested resources include fact sheets, publications, news releases, reports, and websites of government agencies. Recent (published within the past 10 years) peer-reviewed journals of health and science may also be used, as well as *Contraceptive Technology, 20th Revised Edition*.

Contraceptives

AIDS.gov on Polyurethane and Polyisoprene Condoms
http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/sexual-risk-factors/

Centers for Disease Control and Prevention (CDC) on Contraception
http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm

CDC on Condoms
http://www.cdc.gov/condomeffectiveness/brief.html

CDC on Natural (lambskin) Condoms
http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception.htm and
http://www.cdc.gov/std/tg2015/clinical.htm

CDC on Polyurethane Condoms
http://www.cdc.gov/std/tg2015/clinical.htm

Food and Drug Administration (FDA) on Birth Control
http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm

FDA Labels on Specific Contraceptives (Including Nexplanon, Skyla, etc.)
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (Type in drug name)

FDA on Condoms and Sexually Transmitted Diseases
http://www.fda.gov/ForConsumers/byAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm126372.htm

* Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D, Policar MS. Contraceptive Technology: Twentieth Revised Edition. New York NY: Ardent Media, 2011. http://www.contraceptivetechnology.org/CTFailureTable.pdf and http://www.contraceptivetechnology.org/table.html

National Institutes of Health (NIH)/Medline on Birth Control
http://www.nlm.nih.gov/medlineplus/birthcontrol.html (Including the Medical Encyclopedia on right side of screen); and
http://www.nichd.nih.gov/health/topics/contraception/conditioninfo/Pages/types.aspx

U.S. Medical Eligibility Criteria for Contraceptive Use
http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm

WomensHealth.Gov on Birth Control
http://womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.html

* When making recommendations regarding efficacy/failure rates of contraceptives, please refer to Contraceptive Technologies: Twentieth Revised Edition.

Reproductive Health

Cancer.gov on Reproductive Anatomy
http://training.seer.cancer.gov/anatomy/reproductive/

CDC on Reproductive Health Data and Statistics (including teen pregnancy)
http://www.cdc.gov/reproductivehealth/Data_Stats/index.htm

GirlsHealth.Gov Glossary
http://www.girlshealth.gov/glossary/websiteGlossary.html

GirlsHealth.Gov on Reproductive Health, Puberty, and Menstruation
http://www.girlshealth.gov/body/index.html

National Cancer Institute on Pelvic Exams, Pap Tests, and Genital Tract
http://www.cancer.gov/cancertopics/factsheet/Detection/Pap-test
http://training.seer.cancer.gov/anatomy/reproductive/female/tract.html

NIH/Medline Encyclopedia
http://www.nlm.nih.gov/medlineplus/encyclopedia.html

NIH/Medline on Female Reproductive System and Menstruation
http://www.nlm.nih.gov/medlineplus/ency/imagepages/19263.htm and
http://www.nlm.nih.gov/medlineplus/menstruation.html

NIH/Medline on Male Reproductive System and Sperm Release Pathway
http://www.nlm.nih.gov/medlineplus/ency/anatomyvideos/000121.htm

Office of Adolescent Health (OAH) on Reproductive Health
http://www.hhs.gov/ash/oah/adolescent-health-topics/reproductive-health/

WomensHealth.Gov Glossary
http://womenshealth.gov/glossary/

WomensHealth.Gov on Reproductive Health, Menstruation, and Pap Tests
http://www.womenshealth.gov/publications/our-publications/the-healthy-woman/reproductive_health.pdf and
http://www.womenshealth.gov/publications/our-publications/fact-sheet/menstruation.html and
http://www.womenshealth.gov/publications/our-publications/fact-sheet/pap-test.html

Sexually Transmitted Diseases/Infections

CDC 2015 STD Treatment Guidelines
http://www.cdc.gov/std/tg2015/default.htm

CDC STD Data and Statistics
http://www.cdc.gov/std/stats/default.htm

CDC Fact Sheet: Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the
United States (Feb. 2013)
http://www.cdc.gov/std/stats/STI-Estimates-Fact-Sheet-Feb-2013.pdf

CDC on HPV Vaccine
http://www.cdc.gov/vaccines/vpd-vac/hpv/default.htm

CDC on STDs (fact sheets, treatment guidelines, reports, etc.)
http://www.cdc.gov/std/

CDC on STD and HIV Screening Recommendations
http://www.cdc.gov/std/prevention/screeningreccs.htm

CDC National Prevention Information Network (NPIN) on STDs
http://www.cdcnpin.org/scripts/std/index.asp

GirlsHealth.Gov on STIs
http://www.girlshealth.gov/body/sexuality/sti.html

OAH on STDs
http://www.hhs.gov/ash/oah/resources-and-publications/info/parents/just-facts/stds.html

NIH on STDs
http://health.nih.gov/topic/SexuallyTransmittedDiseases/WomensHealth and
http://www.nichd.nih.gov/health/topics/stds/conditioninfo/Pages/types.aspx

WomensHealth.Gov on STDs
http://womenshealth.gov/publications/our-publications/fact-sheet/sexually-transmitted-infections.html?from=AtoZ

Teen Pregnancy

CDC on Reproductive Health Data and Statistics (including teen pregnancy)
http://www.cdc.gov/reproductivehealth/Data_Stats/index.htm#TeenPreg

CDC on Teen Pregnancy
http://www.cdc.gov/TeenPregnancy/index.htm

CDC National Center for Health Statistics, Key Findings from the 2011-2013 National Survey of Family Growth (focus on Sexual Activity, Contraceptive Use, and Childbearing of Teenagers Aged 15–19 in the United States) - http://www.cdc.gov/nchs/data/databriefs/db209.htm

National Center for Health Statistics: Birth Data - http://www.cdc.gov/nchs/births.htm

NIH/Medline on Teenage Pregnancy
http://www.nlm.nih.gov/medlineplus/teenagepregnancy.html

HIV/AIDS

AIDS.gov
http://www.aids.gov/

CDC on HIV (including prevention, transmission, testing, treatment, statistics, etc.)
http://www.cdc.gov/hiv/

CDC Fact Sheets on HIV/AIDS (by population, testing, treatment, etc.)
http://www.cdc.gov/hiv/resources/factsheets/index.htm#Prevention

CDC on HIV Testing in the U.S.
http://www.cdc.gov/nchhstp/newsroom/docs/HIV-Testing-US-508.pdf

CDC Vital Signs – HIV Among Youth in the U.S.
http://www.cdc.gov/vitalsigns/HIVAmongYouth/index.html

FDA on HIV/AIDS Testing
http://www.fda.gov/ForPatients/Illness/HIVAIDS/Prevention/ucm117922.htm

NIH on HIV Treatment and ATRs
http://www.niaid.nih.gov/topics/hivaids/understanding/treatment/pages/default.aspx; and
http://www.niaid.nih.gov/topics/HIVAIDS/Understanding/Treatment/Pages/arvDrugClasses.aspx
and
http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf

Adolescent Health and Risk Behaviors

CDC Division of Adolescent and School Health (DASH)
http://www.cdc.gov/HealthyYouth/

      Adolescent Health: http://www.cdc.gov/HealthyYouth/AdolescentHealth/index.htm

      Sexual Risk Behaviors: http://www.cdc.gov/HealthyYouth/sexualbehaviors/index.htm

      Youth Risk Behavior Surveillance System (YRBSS):
      http://www.cdc.gov/HealthyYouth/yrbs/index.htm

CDC on STD Stats among Teens and Young People
http://www.cdc.gov/std/stats13/adol.htm

GirlsHealth.Gov on Adolescent Sexuality, Birth Control, STIs, Abstinence, etc.
http://www.girlshealth.gov/body/sexuality/index.html

NIH/Medline on Teen Sexual Health
http://www.nlm.nih.gov/medlineplus/teensexualhealth.html

Other

CDC's NCHHSTP Fact Sheets (HIV prevention, testing, and prevalence; STD statistics, and more)
http://www.cdc.gov/nchhstp/newsroom/FactSheets.html

CDC on Contraceptive Methods Women Have Ever Used: United States, 1982–2010
http://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf

CDC on Use of Emergency Contraception Among Women Aged 15–44: United States, 2006–2010
http://www.cdc.gov/nchs/data/databriefs/db112.pdf

CDC STD Vaccines
http://www.cdc.gov/std/prevention/default.htm
http://www.cdc.gov/vaccines/schedules/index.html

CDC, National Center for Health Statistics, National Survey of Family Growth
http://www.cdc.gov/nchs/nsfg.htm

CDC National Health Statistics Report: Current Contraceptive Use in the United States, 2006–2010, and Changes in Patterns of Use Since 1995
http://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf

CDC National Health Statistics Report: Sexual Behavior, Sexual Attraction, and Sexual Identity in the United States: Data From the 2006–2008 National Survey of Family Growth
http://www.cdc.gov/nchs/data/nhsr/nhsr036.pdf

CDC MMWR – Prepregnancy Contraceptive Use Among Teens with Unintended Pregnancies Resulting in Live Births, PRAMS 2004-2008 (January 20, 2012 Report)
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6102a1.htm

CDC NPIN on Parents Involvement
http://www.cdcnpin.org/parentsmatter/index.asp

FDA Office of Women's Health
http://www.fda.gov/ForConsumers/byAudience/ForWomen/default.htm

FDA Vaccination Related Information
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm

NIH/Medline on Teen Development
http://www.nlm.nih.gov/medlineplus/teendevelopment.html

General Sites

AIDS.Gov
http://www.aids.gov/

Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/

CDC Division of Adolescent and School Health (DASH)
http://www.cdc.gov/HealthyYouth/

CDC Morbidity and Mortality Weekly Reports (MMWR)
http://www.cdc.gov/mmwr/

CDC National Prevention Information Network (NPIN)
http://www.cdcnpin.org/

GirlsHealth.Gov
http://www.girlshealth.gov/

National Institutes of Health (NIH)
http://www.nih.gov/

National Institute of Health on Alcohol Abuse and Alcoholism (NIAAA)
http://www.niaaa.nih.gov/

National Institute on Drug Abuse (NIDA)
http://drugabuse.gov/nidahome.html

Office of Adolescent Health (OAH)
http://www.hhs.gov/ash/oah/

Office of Population Affairs
http://www.hhs.gov/opa/

U.S. Food and Drug Administration (FDA)
http://www.fda.gov/

U.S. National Library of Medicine (Medline Plus)
http://www.nlm.nih.gov/medlineplus/

WomensHealth.Gov
http://www.womenshealth.gov/

Updates/News Releases/Journal Articles:

Info on antibiotic-resistant gonorrhea
http://www.cdc.gov/std/gonorrhea/arg/default.htm and
http://www.cdc.gov/nchhstp/newsroom/docs/Gonorrhea-Treatment-Guidelines-FactSheet.pdf

FDA approves One-Step emergency contraceptive for use without a prescription for all ages
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082

Condom Use by Adolescents (addresses dual method use as well) – Pediatrics Volume 132,
Number 5, November 2013
http://pediatrics.aappublications.org/content/early/2013/10/23/peds.2013-2821.full.pdf

Dual Use of Condom and Other Contraceptive Methods among Adolescents and Young Women
in the U.S. http://www.jahonline.org/article/S1054-139X(13)00424-2/abstract?source=aemf

Nexplanon replaces Implanon - Journal of Family Planning and Reproductive Health Care:
http://jfprhc.bmj.com/content/36/4/187

Prevalence of Sexually Transmitted Infections Among Female Adolescents Aged 14 to 19 in the United States (Pediatrics 2009 article)
http://pediatrics.aappublications.org/content/124/6/1505.full.pdf

Gynecologic Examination for Adolescents in the Pediatric Office Setting (Pediatrics 2010 article) http://pediatrics.aappublications.org/content/126/3/583.full