# Supporting Statement Part A

# U.S. Department of Health and Human Services

# ASPA COVID-19 Public Education Campaign Market Research

**(OMB Control No. ####-New)**

**Justification**

* 1. Need and Legal Basis

In accordance with 5 CFR 1320.13, the United States Department of Health and Human Services (HHS) plans to submit an emergency processing submission. As a general matter, under sections 1320 (a)(2)(ii) and (2)(iii) of the federal regulations, an emergency processing may be authorized in the occurrence of an unanticipated event and the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Given the impact of the COVID-19 pandemic on the nation, the Secretary of Health and Human Services (HHS) has also declared a public health emergency effective January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d [1]) and renewed it continually since its issuance (see links to the determination [here](https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx) and [here](https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency)).

* 1. Information Users

This submission contains three parts: 1. COVID-19 Current Events Tracker; 2. Foundational Focus Groups; and 3. Copy Testing Surveys. The broad purpose of each effort is as follows:

*Current Events Tracker*

The primary purpose of the COVID-19 Current Events Tracker (CET) survey is to continuously track key metrics of importance to the Campaign, including vaccine confidence, familiarity with and trust in HHS, and the impact of external events on key attitudes and behaviors. Tracking Americans’ attitudes about, perceptions of, and behavior toward the COVID-19 pandemic will inform the Campaign of key metrics around vaccine confidence and uptake, as well as towards vaccine messengers such as HHS and key public health officials. It will also inform changes in messaging strategies necessary to effectively reach the entire U.S. population or specific subgroups.

The weekly tracking of this information will be critical for the Campaign’s ability to respond to shifting events and attitudes in real-time, helping guide the American public with accurate information about the vaccine rollout as well as on how to take protective actions against COVID-19.

*Foundational Focus Groups*

The office of the Assistant Secretary for Public Affairs (ASPA) is collecting information through the COVID-19 Public Education Campaign Foundational Focus Groups to inform the Campaign about audience risk knowledge, perceptions, current behaviors, and barriers and motivators to healthy behaviors (including COVID-19 vaccination). Ultimately these focus groups will provide in-depth insights regarding information needed by Campaign audiences as well as their attitudes and behaviors related to COVID-19 and the COVID-19 vaccines. These will be used to inform the development of Campaign messages and strategy.

*Copy Testing Surveys*

Prior to placing Campaign advertisements in market, ASPA will conduct copy testing surveys to ensure the final Campaign messages have the intended effect on target attitudes and behaviors. Copy testing surveys will be conducted with sample members who comprise the target audiences; these surveys will assess perceived effectiveness of the advertisements as well as the effect of exposure to an ad on key attitudes and behavioral intentions. The results from these surveys will be used internally by ASPA to inform decisions on Campaign messages and materials; for example, to identify revisions to the materials or determine which advertisement to air.

* 1. Use of Information Technology

*Current Events Tracker*

The CET will be administered online by a survey panel vendor (Ipsos KnowledgePanel) as part of an omnibus survey that includes questions from other organizations. The CET questions are expected to comprise the majority of the questions in the survey from week to week, but a small number of questions sponsored by other Ipsos’ clients may be included in the full survey. The survey vehicle is designed to be flexible to accommodate many different clients. Often the questions fielded as part of the omnibus are topical in nature and could cover topics such as views of events in the news; however, the additional clients and survey questions included in the omnibus survey over the next two years is not known at this time.

Panel members will be invited to the survey through email invitations and reminders (provided in Attachment B) and will be asked to log-in to the panel vendor portal to complete the survey. The survey minimizes respondent burden by using clear and easy to read pages with minimal graphics to make it as easy as possible to respond to questions. The survey also incorporates skip logic so respondents automatically skip past any questions that are not applicable to them.

Members of the Ipsos KnowledgePanel update their personal information with the panel vendor on a regular basis, meaning that the vendor collects several additional demographic variables which are available to ASPA. For this effort, ASPA will obtain relevant demographic variables (e.g., age, education, race/ethnicity, gender, household size, household type, household income, census regions, marital status) from the panel vendor to help minimize the number of questions asked in the survey, thus reducing burden.

*Foundational Focus Groups*

For the HHS COVID-19 Public Education Campaign Foundational Focus Groups, eight rounds of 18 focus groups (with 4-6 participants per group) will be conducted remotely using teleconference software. Vendors will recruit participants from their panel databases via invitation emails and a screener questionnaire (Attachments D and E) to participate in the groups*.* Vendors will generally screen participants via phone, but an online version of the screener may be used in the event that vendors are having challenges meeting their quotas for the groups by using telephone screening only. If an online screener is used, the questions will be programmed to appear exactly the same way as they are asked in the telephone screener.

*Copy Testing Surveys*

The copy testing surveys will be administered online by a survey panel vendor (Prodege). Panel members have already agreed to be contacted for surveys and have provided Prodege with their demographic information to use for the purposes of sampling for specific surveys. Prodege will initially screen panel members on basic demographics, such as age and ethnicity, based on information within their existing dataset and invite potential participants to the survey through email invitations and reminders (Attachment I). Potential participants will be asked to log-in to the panel vendor web portal to enter the survey, at which point they will answer additional screening questions. These requirements include not working for the U.S. Federal government or media marketing fields, not having participated in a COVID-19 vaccine trial, and not having received two doses of the COVID-19 vaccine. If participants pass the screener questions at the beginning of the survey, they will view the informed consent form (Attachment H) and then complete the remainder of the survey. Participants who do not pass the screener questions embedded at the beginning of the survey will be screened out and thanked for their time. The survey minimizes respondent burden by using clear and easy to read pages with minimal graphics to make it as easy as possible to respond to questions. The survey also incorporates skip logic so respondents automatically skip past any questions that are not applicable to them. Respondents will be randomly assigned to one test condition in which they are shown a subset of the advertisements that are being tested in the study, thus minimizing the number of creative assets a respondent views and reacts to.

* 1. Duplication of Efforts

The team has not identified any duplicative information collection instruments or processes.

Within the ASPA COVID-19 Public Education Campaign research efforts, the CET assesses broad perceptions and attitudes across the general public to form foundational knowledge to inform the campaign and ASPA. Other third-party survey work focuses on specific topics or outcomes and is not geared to provide the information that is needed to develop an understanding of the audience’s needs and preferences for information that will be disseminated as part of this campaign. The CET was also designed to be able to change rapidly to meet emergent needs of the campaign; for example, to assess the potential influence of external factors that may impact the campaign and cannot be anticipated.

The CET also differs from other surveys being conducted in support of the ASPA COVID-19 Public Education Campaign. Specifically, the CET differs from the Monthly Outcome Survey (MOS), which tracks key campaign variables over time and is not designed to track current events nor foundational aspects of behavior and attitudes towards the pandemic and the COVID-19 vaccine.

While there are other ongoing recurring third-party surveys polling Americans’ behavior and attitudes about the COVID-19 pandemic and vaccine willingness, most of these surveys occur less frequently (typically once or twice a month) or are single administration surveys. Additionally, none of these survey projects have a recurring focus on knowledge of and/or attitudes about the U.S. Department of Health and Human Services – in general or as they pertain to the COVID-19 pandemic and this public education campaign.

One exception is the robust, daily joint agency information collection spearheaded by the U.S. Census Bureau to measure COVID-19 impacts, the Household Pulse Survey (Pulse). In many ways, this is an ideal vehicle, but the primary drawback is the inability to add questions regarding impactful events as they occur. In fact, the first opportunity to add any questions comes in March 2021. Through communications with the Pulse team, we will continue to explore adding key tracking items when feasible, and removing those items from the CET. This approach allows the program to maintain a vehicle appropriate to respond to unanticipated in-market events while also minimizing the number of questions on (CET) and the respondent burden.

Note: ASPA submitted a prior emergency package (0990-0475). The research efforts covered in that package (longitudinal and cross-sectional campaign evaluations) and those covered herein work in concert to support the HHS COVID-19 Public Education Campaign. There are no duplications between these two submissions.

* 1. Small Businesses

All efforts described in this submission (CET, Foundational Focus Groups, and Copy Testing Survey) will be completed by individuals and not by any organizations, and therefore are not anticipated to impact small businesses.

* 1. Less Frequent Collection

*Current Events Tracker*

This request is voluntary. Sampled members can choose to respond or not respond to the surveys with no penalty for not responding. Data collected through the CET data collection efforts will help ASPA and the Campaign understand changing public perceptions and attitudes towards COVID-19 as well as identify any emergent issues among target groups within the general population. The survey will be conducted on a weekly basis so that the team can track metrics over time such as vaccine confidence, perceptions about organizations providing information about COVID-19 and vaccines, and the use of preventative measures to slow the spread of the virus.

*Foundational Focus Groups*

This request is voluntary. Individuals who are invited to and screened for the focus groups have the option to not accept the invitation to participate with no penalties attributed to them. Data collected through the focus groups will provide ASPA in-depth information on vaccine confidence, preventative measures taken to slow the spread of infection, and information sources used by people to educate themselves on issues surrounding COVID-19. This information will be used to inform the Campaign in developing and targeting its messaging. These focus groups will be conducted on roughly a quarterly basis. If the information were collected less frequently, the Campaign may miss out on insights regarding how attitudes change over time, or how the public reacts to key events related to COVID-19 and the COVID-19 vaccine. Given how the COVID-19 pandemic and response have evolved over time, it is important for the Campaign to maintain an ongoing awareness of the public’s in-depth perceptions and motivations as they relate to Campaign-targeted behavior.

*Copy Testing Surveys*

This request is voluntary. Sampled members can choose to respond or not respond to the surveys with no penalty for not responding. Up to eight copy testing surveys will be fielded over the course of the Campaign; these will be timed to coincide with the production schedule for each Wave of Campaign messaging. In order to be effective, copy testing must be conducted for each Wave of materials, as each Wave will have a unique message and creative approach. If copy testing were not conducted for any Wave of the Campaign, then we would not be able to proactively determine whether the ads are likely to affect the target behaviors in the desired manner. Success of the Campaign hinges upon being able to test creative assets before placing them in market.

* 1. Special Circumstances

There are no special circumstances associated with this collection.

* 1. Federal Register/Outside Consultation

On March 11, 2021, OMB-0990-0476 was published in the Federal Register for a 60-day public comment period [Document Citation 86 FR 13907; Pages 13907-13908; Document number 2021-05040]. One comment was received on May 7, 2021, HHS/Angel Sepulveda, asking if the collection of information will include a data set of inform the educational level of understanding of the people, and the commenter provided some suggestions. On May 27, HHS/ASPA responded that all messaging is designed to be clear, concise, and written in plain language and that surveys are used to assist in garnering people’s knowledge about COVID-19 vaccines, barriers and motivators to vaccination, attitudes, and trusted messengers all broken out by various demographic characteristics.

* 1. Payments/Gifts to Respondents

*Current Events Tracker*

Ipsos KnowledgePanel has their own rewards program that provides panel members with points for completing surveys, which can be redeemed for gift cards or merchandise. These small tokens of appreciation will help maximize response rates across a more diverse respondent pool.

For the CET, respondents will receive the equivalent of $1 in points for completing the survey. Incentives are important for the CET because the survey fielding window is relatively short and the number of required completes is relatively high. Providing incentives will allow the survey vendor to recruit a sufficient number of respondents during the fielding window.

*Foundational Focus Groups*

OMB guidance currently sets the incentive for in-person focus groups at $75. Due to COVID-19, these focus groups must be virtual, which would typically warrant a lower incentive payment. However, HHS requests that participants in these focus groups receive a payment of $75 for participation in one 90-minute virtual focus group.

Providing incentives for recruitment of focus group participants is a critical component of planning a successful recruitment effort. Given the critical need to get consistent messaging out to the public as soon as possible, ensuring incentives are high enough will support successful recruitment of all participants, which is imperative especially for those groups disproportionately affected by COVID-19.

Although initially it may appear as a cost savings to have a lower incentive amount, in the long term it takes more resources to recruit respondents to attend a focus group with a lower incentive. For instance, with a lower incentive it may require 10 calls before securing a participant while a higher incentive may require only half of those calls. A higher incentive also reduces the number of no-shows, which also means we will have fewer focus group cancellations (we cannot run focus groups with fewer than 4 participants).

*Copy Testing Surveys*

Prodege’s incentive program is Swagbucks, an online reward community in which members can earn and accumulate virtual currency that can be redeemed for gift cards to popular retailers (online and offline) or used for donations toward charities. Respondents will receive the equivalent of $5.00 in Swagbucks for completing the copy testing survey. Providing incentives allows the survey vendor to recruit a sufficient number of respondents within the expedited fielding window.

* 1. Confidentiality

*Current Events Tracker*

ASPA will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. ASPA will not have access to any identifying information for respondents to the CET. Ipsos provides their members with confidentiality assurances when they agree to become members of the survey panels and does not release personally identifying information to data users.

The Ipsos KnowledgePanel member “Bill of Rights” (Attachment A) states that responses will be anonymized, and each participant will be assigned a unique ID. Express permission from participants is required for Ipsos to share identifying information with a survey client. KnowledgePanel members are informed that participation in surveys is voluntary and that they do not have to answer any questions they do not wish to answer.

*Foundational Focus Groups*

ASPA will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. ASPA will not have access to any identifying information for participants in the foundational focus groups. Participants’ identity will not be linked to their individual responses and all findings will be reported in the aggregate. The data collected, including information collected during screening, video/audio files from the focus groups, and transcripts, will be stored on a password-protected computer and/or in locked cabinets that only the project team can access.

*Copy Testing Surveys*

ASPA will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. ASPA will not have access to any identifying information for respondents to the copy testing survey. Prodege provides their members with confidentiality assurances when they agree to become members of the survey panels and does not release personally identifying information to data users. In addition, all data obtained from respondents is stored on secure servers only accessible to the immediate research team. All study related data files use encryption and password protection so that only authorized personnel can access the files.

* 1. Sensitive Questions

*Current Events Tracker*

The survey questions are not sensitive in nature. The general perceptual or attitudinal questions on this survey instrument are not expected to pose any psychological risks to respondents. However, survey questions about COVID-19 may make participants feel uncomfortable or bring up unwanted thoughts or feelings. To minimize these risks, we will emphasize the voluntary and confidential nature of the research and restate the panel vendor’s commitment to confidentiality within the survey.

*Foundational Focus Groups*

The foundational focus groups pose no more than minimal risk to subjects. None of the questions/items/data elements in the foundational focus groups will include private or sensitive information. However, questions about COVID-19 may make participants feel uncomfortable or bring up unwanted thoughts or feelings. To minimize these risks, we will emphasize the voluntary and confidential nature of the research in the informed consent form and again at the beginning of each focus group. Additionally, in the event participants experience any distress from this study, we will provide contact information for the 1) SAMHSA Disaster Distress Helpline, which provides 24/7 crisis counseling and support for individuals experiencing emotional distress caused from natural or human-caused disasters, as well as the 2) Suicide Prevention Lifeline (a 24/7 free and confidential support resource) in the informed consent form (Attachment F

*Copy Testing Surveys*

The survey questions are not sensitive in nature and are not expected to pose any psychological risks to respondents. However, survey questions about COVID-19 may make participants feel uncomfortable or bring up unwanted thoughts or feelings. To minimize these risks, we will emphasize the voluntary and confidential nature of the research and restate the panel vendor’s commitment to confidentiality within the survey. In addition, the informed consent form includes mental health resources in case of unexpected discomfort experienced during the survey. (The informed consent form is provided in Attachment H of this submission).

* 1. Burden Estimates (Hours & Wages)

*Current Events Tracker*

For the CET we estimate that 1,000 complete respondents x 0.12 hours per complete survey submission = approximately 120 burden hours associated with completing this survey each wave. No separate screening of participants will be required because Ipsos stores panel variables that determine the eligibility of each panel member without the need for a screener instrument. Only eligible panel members will be invited to take the survey. Over 92 total waves, the total burden is estimated to be approximately 11,040 total burden hours.

|  |  |  |  |
| --- | --- | --- | --- |
| **Category of Respondent** | **No. of Respondents per Wave** | **Participation Time (Hours)** | **Burden Hours per Wave** |
| Survey Completes: Adults 18+ | 1,000 | 0.12 | 120 |
| **Total, all Waves (92)** | **92,000** | **0.12** | **11,040** |

*Foundational Focus Groups*

For the foundational focus groups, we estimate screening 2,500 potential respondents x .09 hours (5 minutes) = 225 hours associated with screening focus groups participants during each round. In addition, the focus groups will include 108 respondents x 1.5 hours per focus group = 162 burden hours associated with the discussion for each round of focus groups. Over the course of the Campaign, this will amount to eight rounds of focus groups, for a total of 3,096 burden hours.

|  |  |  |  |
| --- | --- | --- | --- |
| **Category of Respondent** | **No. of Respondents per Round** | **Participation Time (Hours)** | **Burden Hours per Round** |
| FG Screening: Adults in the “movable middle” | 1,250 | 0.09 | 112.5 |
| FG Screening: Adults in priority populations | 1,250 | 0.09 | 112.5 |
| FG Participants: Adults in the “movable middle” | 54 | 1.5 | 81 |
| FG Participants: Adults in priority populations | 54 | 1.5 | 81 |
| **Total, per round** | **2,500\*** | **.1548\*\*** | **387** |
| **Total, all rounds (8)** | **20,000\*** | **.1548\*\*** | **3,096** |

\*Focus group participants are also included in the focus group screening, so are only counted once toward the total number of respondents.

\*\*.1548 is approximately 9.3 minutes; it is the weighted average over the screener and survey for all participants.

*Copy Testing Surveys*

For the copy testing survey, we estimate screening 6,700 potential respondents x .03 hours (2 minutes) = 201 hours associated with screening survey participants during each wave. In addition, we will obtain 1,000 respondents x .33 hours (20 minutes) per submission = 330 hours associated with completed surveys in each wave of Campaign message testing. Over the course of the Campaign, this will amount to eight survey Waves, for a total of 4,248 burden hours.

|  |  |  |  |
| --- | --- | --- | --- |
| **Category of Respondent** | **No. of Respondents per Wave** | **Participation Time (Hours)** | **Burden Hours per Wave** |
| Survey Screener: Adults 18+ | 6,700 | 0.03 | 201 |
| Survey Completes: Adults 18+ | 1,000 | 0.33 | 330 |
| **Total, one Wave** | **6,700\*** | **.07925** | **531** |
| **Total, all Waves (8)** | **53,600\*** | **.07925** | **4,248** |

\*Survey completes are also included in the survey screener, so are only counted once toward the total number of respondents.

\*\*.07925 is approximately 4.8 minutes; it is the weighted average over the screener and survey for all participants.

**Sum of All Studies**

**TOTAL RESPONDENTS: 165,600**

**TOTAL BURDEN HOURS: 18,384**

* 1. Capital Costs

There are no direct costs to respondents other than their time to participate in the study.

* 1. Cost to Federal Government

*Current Events Tracker*

The survey will field weekly for two years, for a total of 92 waves, using a panel vendor and will collect an estimated 92,000 responses from participants in total. The total labor price is $536,028.80 with $1,142,300.00 additional for ODCs. Broken down, the price for one wave of the CET is $5,826.40 in labor costs and $12,416.30 in ODCs associated with survey fielding. This price reflects the labor and direct costs to field 92 waves of a 7-minute online survey to 1,000 total participants from the Ipsos KnowledgePanel. Included in these costs are: 1) Development of the annotated questionnaire; 2) Panel vendor services to program and test the survey, field the survey, staff the survey helpline, deliver data tables, and clean and deliver data; 3) Profile variables from the panel vendor; 4) IRB review; 5) Analysis and reporting (key findings included in the Weekly Situation briefing) and 6) Quality control.

*Foundational Focus Groups*

In total, ASPA plans to conduct eight rounds of foundational focus groups with each round comprised of 18 focus groups. The total labor costs to conduct eight groups is $1,080,894.72 and $455,513.76 in ODCs. Broken down, the price for one round of foundational focus groups is $135,111.84 in labor costs and $56,939.22 in other direct costs, including participant incentives.

Included in these costs are: 1) Development of the focus group screener; 2) Development of the focus group discussion guide; 3) Translation of materials into Spanish; 4) IRB review; 5) Participant recruitment; 6) Participant incentives; 7) Execution of the focus groups and moderation; 8) Live interpretation of the two Spanish-speaking groups for those in the virtual back room; 9) Transcription; 10) Analysis and reporting (memo of key findings and recommendations); 11) Quality control.

*Copy Testing Surveys*

The copy testing survey will field for eight waves using a panel vendor and will collect an estimated 8,000 responses from participants in total. The total labor price for the eight waves is $731,877.36 with $128,550.00 additional for ODCs. Broken down, the price for each wave of the copy testing survey is $91,484.67 in labor costs and $16,068.75 in ODCs associated with survey fielding. This price reflects the labor and direct costs to field eight waves of a 20-minute online survey to 8,000 total participants. Included in these costs are: 1) Development of the annotated questionnaire; 2) Panel vendor services to program and test the survey, field the survey, staff the survey helpline, deliver data tables, and clean and deliver data; 3) Participant incentives; 4) IRB review; 5) Analysis and reporting (memo of key findings and recommendations) and 6) Quality control.

**TOTAL COST TO THE GOVERNMENT: $4,075,164.64**

* 1. Changes to Burden

This is a new information collection request.

* 1. Publication/Tabulation Dates

*Current Events Tracker*

The aim of this survey is to understand the public’s information sources, attitudes, and behaviors as they relate to COVID-19 and COVID-19 preventative behaviors to include vaccination. The data will be used internally to inform the development of Campaign messages and to guide strategy. After each survey wave has been completed, results will be presented in weekly data tables and briefing slides that will be used by ASPA and the Campaign team. We do not expect to publish external briefings or reports from this study. We will communicate this to respondents and inform them, should our intentions not to publish external facing materials change. All results will be aggregated and anonymized and explicitly discuss the limitations of this design, including the lack of generalizability beyond the study participants.

*Foundational Focus Groups*

The primary purpose of these focus groups will be to inform HHS COVID-19 Public Education Campaign strategy about audience risk knowledge, perceptions, current behaviors, and barriers and motivators to healthy behaviors. The findings from these focus groups will be used internally to inform the development of Campaign messages and to guide strategy. Key findings and recommendations will be presented in a memo that will be used by ASPA and the Campaign team to inform decision-making and strategy. We will communicate this to respondents and inform them, should our intentions not to publish external facing materials change. All results will be aggregated and anonymized and explicitly discuss the limitations of this design, including the lack of generalizability beyond the study participants.

*Copy Testing Surveys*

The primary purpose of the copy testing surveys is to inform final decisions about Campaign advertisements. These findings will be used internally. A briefing with key findings and recommendations will be provided to ASPA. We do not expect to publish external-facing briefings or reports with the findings from these surveys. We will communicate this to respondents and inform them, should our intentions not to publish external facing materials change. All results will be aggregated and anonymized and explicitly discuss the limitations of this design, including the lack of generalizability beyond the study participants.

* 1. Expiration Date

*Current Events Tracker*

The OMB approval number and expiration date will be shown in the top right corner of all pages of the survey that include CET questions.

*Foundational Focus Groups*

The informed consent form for the foundational focus groups will display the OMB approval number and expiration date.

*Copy Testing Surveys*

The OMB approval number and expiration date will be shown on all pages of the online programmed survey.

* 1. Certification Statement

There are no exceptions to item 19 of OMB Form 83-1.

Attachment A: HHS COVID-19 Public Education Campaign Current Events Tracker Ipsos Consent Form

Attachment B: HHS COVID-19 Public Education Campaign Current Events Tracker Ipsos Communications

Attachment C: HHS COVID-19 Public Education Campaign Current Events Tracker External IRB Determination

Attachment D: HHS COVID-19 Public Education Campaign Foundational Focus Groups Invitation Emails

Attachment E: HHS COVID-19 Public Education Campaign Foundational Focus Groups Screener

Attachment F: HHS COVID-19 Public Education Campaign Foundational Focus Groups Informed Consent Form

Attachment G: HHS COVID-19 Public Education Campaign Foundational Focus Groups External IRB Determination

Attachment H: HHS COVID-19 Public Education Campaign Copy Testing Survey Consent Form

Attachment I: HHS COVID-19 Public Education Campaign Copy Testing Survey Communications

Attachment J: HHS COVID-19 Public Education Campaign Copy Testing Survey External IRB Determination