# BD-STEPS Stillbirth Pilot Protocol

## Purpose

Birth defects affect about 1 in 33 pregnancies and account for one in five infant deaths and contribute substantially to childhood morbidity and long-term disability. Currently, the causes of about two-thirds of all birth defects are unknown. Identifying risk factors for birth defects can provide valuable information to pregnant women and their healthcare providers (aid in making treatment decisions.) Additionally, in the United States, there are about 26,000 stillbirths (pregnancy loss at 20 or more weeks of gestation) each year, nearly equal to the number of infant deaths.

Significant racial disparities exist in the occurrence of stillbirths, with non-Hispanic Black women at much higher risk of having a stillbirth than non-Hispanic White women. Older mothers over the age of 35 are also at greater risk for stillbirths. Improved understanding of the causes of stillbirths will inform public health prevention efforts.

CDC coordinates a birth defects research program entitled Centers for Birth Defects Research and Prevention (CBDRPs). Under the CBDRP program, CDC coordinated a former case-control research project entitled the National Birth Defects Prevention Study (NBDPS) and a current CBDRP project entitled the Birth Defects study to Explore Pregnancy exposureS (BD-STEPS) to investigate potential causes of birth defects. The current BD-STEPS project includes fetuses/infants with at least one of 17 eligible birth defects, regardless of the pregnancy outcome, but does not include stillbirths without birth defects. However, the existing infrastructure of BD-STEPS provides an opportunity to investigate risk factors for stillbirths without birth defects. In collaboration with CDC, two centers (Massachusetts and Arkansas) have been funded to expand their current activities under FOA #DD13-003 (2016-2018) to include stillbirths without birth defects. With a second round of BD-STEPS funding (2018-2023) RFA-DD-18-001 – Component B, the CBDRP collaborative will continue to expand on the knowledge learned from the activities of BD-STEPS to date.

## Case Definition, Ascertainment and Eligibility

**Definition**

For the purposes of the stillbirth risk factor research activities described in FOA DD14-004 and RFA-DD-18-001, the following definitions apply:

a) A stillbirth is an intrauterine fetal death that occurs at a gestational age of 20 weeks or greater or if the gestational age is unknown then fetal death weighing 500 grams or more at delivery.

b) A fetal death is defined as death before the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

c) A live birth means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

d) An induced termination of pregnancy means the purposeful interruption of an intrauterine pregnancy with the intention other than to produce a live born infant and which does not result in a live birth. This definition excludes management of prolonged retention of products of conception following fetal death.

**Case Ascertainment**

Cases in MA and AR will be identified using the same surveillance infrastructure in place for BD-STEPS using the fetal death records as a source. AR will also utilize vital records, hospital delivery logs, and stillbirth logs. Women who had a stillbirth without birth defect and who reside in the study catchment area during the study period will be eligible to be included in the study.

<u>Arkansas</u>

Arkansas Reproductive Health Monitoring System (ARHMS), an integral component of the Arkansas Center, has served the state for more than 30 years with population-based surveillance of live births, fetal deaths, and prenatal diagnoses of birth defects among Arkansas residents. ARHMS conducted surveillance in limited regions of the state in 1980 and began statewide surveillance in 1993. As the third-oldest birth defects surveillance program in the country, the growth of ARHMS into one of the leading state birth defect surveillance programs in the US has been recognized repeatedly by the Pew Environmental Health Commission at Johns Hopkins School of Public Health. ARHMS, through state legislative authority stipulated by Act 214 of 1985, monitors adverse pregnancy outcomes, including birth defects in Arkansas and grants access to medical records, vital statistics, and personal identifying characteristics necessary to link infants to multiple sources of health-related data.

AR will utilize the high-risk obstetrical and maternal-fetal medicine clinics to capture all hospital-based births and stillbirths from these providers by accessing medical records at the

birthing facilities within the state. Furthermore, AR will access post-mortem or pathology logs at all pathology departments in Arkansas, as well as, ascertainment of pregnancy outcomes from labor and delivery and stillbirth logs from 43 hospitals and birthing centers. Lastly, AR will use state fetal death records on a monthly basis to identify new cases of stillbirths without birth defects, UAMS ANGELS teleultrasound system, and emergency room department records.

Massachusetts

Established in 1996, the Massachusetts Center for Birth Defects Research and Prevention (MCBDRP) is collaboration between the Massachusetts Department of Public Health (MDPH), Boston University's Slone Epidemiology Center (SEC), and Brigham and Women's Hospital Active Malformations Surveillance Program (BWH). MCBDRP is responsible for the collection of information regarding all newly diagnosed cases of birth defects to Massachusetts residents through the MA Birth Defects Monitoring Program (BDMP). BDMP is an active birth defects surveillance system that covers the entire state of MA and is mandated by state legislation enacted in 1963 (Massachusetts General Laws, Chapter 111, Section 67E). The catchment area for BD-STEPS includes Essex, Middlesex, Worcester, Suffolk, Norfolk, Plymouth, and Barnstable Counties and accounts for 81% of the live births in MA.

MA will identify stillbirths in the following multiple overlapping ways: (1) Stillbirths with and without birth defects that occurred within the preceding month are electronically reported by hospitals directly to the MA BDMP as part of mandated birth defects reporting (reportable ICD-9 codes are: V27.1, .3, .4, .6, .7, .9, V32.0-V32.2, V35.0-V35.2, V35.0-V35.2, V36.0-V36.2, 656.40, .41, .43); (2) Fetal deaths at 20 weeks or more gestational age or a weight of 350 grams or more are required to be reported to the MDPH Registry of Vital Records and Statistics within 10 days of the fetal death; and (3) Finally, ten prenatal diagnostic centers in MA report fetuses that are prenatally diagnosed with a potential birth defects monthly to the BDMP along with the pregnancy outcome, if known. This system of prompt reporting in multiple ways helps to ensure that stillbirths are not missed and that they are identified promptly, thus allowing enrollment as early as possible into BD-STEPS. Medical record abstractors from the MA BDMP currently review the maternal medical record for all stillbirths that occur to MA residents to determine if the fetus meets BDMP inclusion criteria. In addition, for stillbirths that occur in the BD-STEPS catchment area, stillbirths without birth defects are reviewed for the purpose of the stillbirth pilot project.

**Inclusion**

To be included in the study as a stillbirth without a major birth defect, the delivery outcome must meet the definition described for a stillbirth as stated above. A fetus may be included if they have birth defects classified as minor according to the Guidelines for Case Classification for the National Birth Defects Prevention Study (Rasmussen et al., Birth Defects Res A Clin Mol Teratol. 2003 Mar;67(3):193-201). Furthermore, a stillbirth resulting after labor is induced for a maternal pregnancy complication such as chorioamnionitis or pregnancy related hypertensive complication may also be included.

Cases will be identified using the same surveillance infrastructure in place for BD-STEPS using sources such as vital records, hospital delivery and stillbirth logs, and high-risk obstetrical clinic data. Mothers with pregnancies having date of delivery (DOD) 7/1/2016 and onwards will be eligible and will be invited to be interviewed. Each CBDRP will interview approximately 100 eligible stillbirth cases with no birth defects each year for inclusion in the study. The cases of mothers with SB without birth defects that have DOD between 7/1/2015 and 6/30/2016, and have been identified, will not be eligible for interview but will be entered into the clinical database and serve as baseline reference data.

Control-infants from each of the CBDRP will be selected randomly from live-born infants without a major birth defect (8), identified either from vital records (birth certificates) or from hospitals of birth, and represent the birth population from which the case infants were identified. Using birth certificates to identify controls is only an option in states where vital records are recorded electronically in a timely manner (generally within weeks of delivery).

Massachusetts: access to these certificates is obtained through data access review according to state laws, and IRB review as needed and Arkansas uses a random sample of the state's birth certificates for control selection. The Arkansas Center has a formal Memorandum of Understanding (updated in 2012) with the Arkansas Department of Health to access vital records information. Additional authority to access these pregnancy-related data was established by the 1985 legislation act for the state's birth defect surveillance system. On a monthly basis, the Health Department selects and delivers a random sample of newly processed birth certificates to serve as potential controls for the Center's research studies.

**Identifying the index pregnancy**

In cases of a multiple gestation pregnancy, the index child will be identified by applying the following rules:

a) A stillbirth with BD-STEPS eligible birth defect takes precedent over other LBs and SBs, regardless of if they have BDs. If there is only one stillbirth with BDSTEPS eligible birth defect in a multiple birth, this case takes priority independent of birth order. If there are two or more of this case in a multiple birth, the eldest takes priority.

b) If there is no stillbirth with a BD-STEPS eligible birth defect in a multiple birth, a live birth with BD-STEPS eligible birth defect takes precedent over other live births and stillbirths w/o or with minor BDs. If there is only one LB with a BD-STEPS eligible birth defect in a multiple birth, this case takes priority independent of birth order. If there are two or more of this case in a multiple birth, the eldest takes priority.

c) If there are no birth defects or minor birth defects are present, the stillbirth w/o or with minor birth defects takes priority over live birth. If there is only one stillbirth without BD or with

minor BD, this case takes priority independent of birth order. If there are two or more of this case in a multiple birth, the eldest takes priority.

- **The case ID will be 1 in the following cases:**
  - 1) case with BD-STEPS-eligible BD (*regardless if index or co-sibling, regardless if LB or SB*))
  - 2) Stillbirth w/o BD
  - 3) Stillbirths w/ minor BD
  - 4) Co-sibling with a BD-STEPS-non-eligible BD

- **The case ID will be 2 in case of controls.**

**Exclusion**

Pregnancy outcomes that meet the definition for an induced termination of pregnancy will not be included, nor will terminations of pregnancy because of the presence of birth defect, unless the birth defects meets criteria for BD-STEPS. These latter cases will be ascertained; however, they will not be included as cases in the stillbirth risk factor research supplemental portion of BD-STEPS.

**Selection of Controls**

MA

The Massachusetts (MA) controls are selected randomly from live births using the birth certificates from MA residents filed with the MA Department of Public Health's Registry of Vital Records. The birth certificates get submitted electronically from the hospitals to Vital Records on a daily basis. From Vital Records data elements get imported into the Bureau of Family Health and Nutrition's Early Childhood Data System within days of birth. We wait approximately two to three months before selecting controls for a given birth month to allows for a greater number of completed birth certificates to be added to the pool of eligible births.

AR

The Arkansas Center uses a random sample of the state's birth certificates for control selection. The Arkansas Center has a formal Memorandum of Understanding (updated in 2012) with the Arkansas Department of Health to access vital records information. Additional authority to access these pregnancy-related data was established by the 1985 legislation act for the state's birth defect surveillance system. On a monthly basis, the Health Department selects and delivers a random sample of newly processed birth certificates to serve as potential controls for the Center's research studies.

Case and control infants are not eligible if:

1) The mother is not a resident of the geographic area covered by one of the CBDRP population-based registries at the time of delivery;
2) The mother is deceased;

3) The mother is incarcerated;
4) The mother participated previously in the NBDPS or BD-STEPS;
5) The mother cannot complete the interview in either English or Spanish;
6) The mother is younger than 15 (or younger than 18 if required by law); or
7) The infant is adopted or in foster care.

## ICD-9-CM Codes

The following codes may be used to assist in identifying cases of stillbirths:

V codes:

V27.1 Single stillborn
V27.3 Twins, one liveborn and one stillborn
V27.4 Twins, both stillborn
V27.6 Other multiple birth, some liveborn
V27.7 Other multiple birth, all stillborn
V31 Twin,mate liveborn
V32 Twin, mate stillborn
V33 Twin, unspecified
V34 Other multiple, mates all liveborn
V35 Other multiple, mates all stillborn
V36 Other multiple, mates live- and stillborn
V37 Other multiple, unspecified
V39 Unspecified

Procedure codes:

69.01 Dilation and curettage for termination of pregnancy
69.02 Dilation and curettage following delivery or abortion
69.51 Aspiration curettage of uterus for termination of pregnancy; Therapeutic abortion NOS
69.52 Aspiration curettage following delivery or abortion
74.91 Hysterotomy to terminate pregnancy; Therapeutic abortion by hysterotomy
75.00 Intra-amniotic injection for abortion

## ICD-10-CM Codes

The following codes may be used to assist in identifying cases of stillbirths.

Z codes:

Z37.1 Single Stillbirth
Z37.3 Twins, one liveborn and one stillborn
Z37.4 Twins, both stillborn
Z37.6 Other multiple birth, some liveborn
Z37.60 Multiple births, unspecified, some liveborn

Z37.69 Other multiple births, some liveborn
Z37.7 Other multiple birth, all stillborn
Z38.3 Twin liveborn infant, born in hospital
Z38.6 Other multiple liveborn infant, born in hospital
Z38.68 Other multiple liveborn infant, delivered vaginally
Z38.69 Other multiple liveborn infant, delivered by c-section
Z38.7 Other multiple liveborn infant, born outside hospital
Z38.8 Other multiple liveborn infant, unspecified as to place of birth
Z37.9 Outcome of delivery, unspecified

Procedure codes:
10A07ZZ Abortion of Products of Conception, Via Natural or Artificial Opening
10A08ZZ Abortion of Products of Conception, Via Natural or Artificial Opening Endoscopic
10D17ZZ Extraction of Products of Conception, Retained, Via Natural or Artificial Opening
10D18ZZ Extraction of Products of Conception, Retained, Via Natural or Artificial Opening Endoscopic
10A00ZZ Abortion of Products of Conception, Open Approach
10A07ZX Abortion of Products of Conception, Abortifacient, Via Natural or Artificial Opening

## Data Collection

### Medical Record Abstraction:

For medical record abstraction, the BD-STEPS clinical database has been modified to include the following information:

- A check box to indicate the case is to be included in the BD-STEPS stillbirth pilot study.
- Placental histopathology results recorded verbatim as a postnatal procedure.
- The presence or absence of fetal maceration recorded as text information in the autopsy field
- Whether the fetal death occurred ante- or intrapartum
- The reason the mother sought medical attention recorded as text information

### Clinical Database [CBDRPClinical_XX.mdb]:

| | SB with BD | SB without BD | Controls |
|---|---|---|---|
| **Stillbirth checkbox** | Checked | Checked | Checked |
| **Clinical review variable** | "BDSTEPS Case" | "Not a BDSTEPS Case" | "BDSTEPS Control" |
| **Participation status** | 500-level code | 500-level code | 500-level code |

**Stillbirth Checkbox**

- All subjects eligible for the stillbirth (SB) supplemental interview should have the stillbirth project check box checked

- SB with birth defects
- SB without birth defects
- Controls

**Clinical Review Variable**

- The clinical review variable in the clinical database should be set to:
  - "BDSTEPS Case" for SB with birth defects
  - "Not a BDSTEPS Case" for SB without birth defects
  - "BDSTEPS Control" for controls

**Participation Status Codes**

- The participation status codes for all subjects eligible for the SB supplemental interview should have a 500-level participation status code
- Subjects who are only part of the SB project – SB without birth defects – will not receive the online occupational questionnaire (OOQ)
  - Online questionnaires are not specified in the SB NOFO
    - SB without a birth defect are not eligible to complete the online occupational questionnaire
  - Once the clinical review variable is properly coded and the SB flag check box is properly used it will be possible for CDC to filter out these subjects before sending links to the Centers

## Administering the Maternal Questionnaires

### Each center will provide data to the CDC-funded interviewing contractor for identifying participants eligible for the BD-STEPS core and stillbirth supplemental questionnaire

MA and AR will share confidential data through the CDC's SAMs Server, including the transfer of CATI and Clinical database files along with the weekly encrypted contact information files. Study collaborators can register for SAMS only by invitation from CDC staff/SAMS manager and only after clearing the SAMS identity proofing process, requiring the submission of two valid forms of photo identification. SAMS has a built-in AES-128 encryption at time of transmission and requires a two-factor authentication process. In addition, SAMS Secure File Transfer (DPS) system uses a 3-tier architecture to shield protected files within the CDC internal network.

### Introduction letters to the two-part BD-STEPS interview: BD-STEPS Core and Supplemental Stillbirth Computer Assisted Telephone Interviews (CATI)

Stillbirths without birth defects will be mailed an Introductory Pre-letter that explains the stillbirth study and how it is integrated into the existing BDSTEPS study (Att37B_SBsupp_PreIntroLetter_Eng). All stillbirths (those with a BD-STEPS eligible birth defect and those without a birth defect) and controls from AR/MA are invited to participate in the two-part CATI through an introductory combined letter (Att37 SBsupp_IntroLetter_Eng or Att37A_SBsupp_IntroLetter-Controls_Eng). The introductory letters contain a $20 gift card thanking them for reviewing the materials. The same procedures are followed as outlined in the BDSTEPS protocol 1.1.1 (Anniversaries when Conducting Mailings). Stillbirths without Birth Defects are mailed this combined letter (Att37) 10 days after their Introductory Pre-Letter has been mailed.

## Thank you/Reminder letters

At the end of the first part of the interview, participants have the option to continue and take the second part, or they can schedule it for a later time. Participants who complete both interviews on the same call will be mailed a thank you packet containing a $30 gift card for completing the first part of the interview and a $20 gift card for completing the second part of the interview (Att44A_ **SBsupp_IntvThankYou-Both_Eng)**. If a participant chooses to complete the second part of the interview at a different time than the first interview, they will receive a thank you letter for the first part of the interview that contains the $30 gift card (Att44B_ **SBsupp_Thank you Letter 1st_Infection and Optional Bloodspot Intro**). This letter reminds them that someone will call them at the scheduled time for the second part of the interview or to schedule a time to take the second part of the interview. These participants will receive an additional Thank You Letter and $20 compensation upon completing the second part of the interview (Att44_ **SBsupp_IntvThankYou-2nd_Eng).**

## Reminders

## Bloodspot and Infectious Disease Linkage Consent Reminder Calls Integrated with SB Interview Reminder Calls

The timeline for the “Bloodspot and Infectious Disease Consent Reminder Calls” will integrate the “SB Interview Reminder Calls” for the Controls who did not schedule the second part of the interview to ensure that the same timeline is followed for the “SB Interview Reminder Calls” for mothers who had a stillbirth with a birth defect.

Please note if the mother had a stillbirth without a birth defect, then the bloodspot and infectious disease linkage consent forms are not sent and any call attempts will be only for participants who did not schedule the supplemental stillbirth interview.

## Call attempts

- Participants who scheduled the second part of the interview will be called at the appointed time.
- Interviewers start making attempts to schedule the second part of the interview about 10 days after Centers (AR, MA) send the Thank You/Reminder Letter for completing the first part of the interview. (Att44B_ **SBsupp_Thank you Letter 1st_Infection and Optional Bloodspot Intro**). Depending on when the BD-STEPS Core CATI interview is completed, reminder calls for the bloodspot and infectious disease linkage consent forms only may be made for participants who are eligible for these parts of the study (Controls and Stillbirhs with Birth Defects). Non-contact attempts result in a delay in subsequent calls to the same phone number for at least 57 hours (see section below: Number and Frequency of Call Attempts)
- Interviewers wait 10 days after making contact with the participant before trying to reach the participant again, to allow time for the Center to remail the needed packet with the bloodspot consent form and/or infectious disease linkage consent form and/or the Thank You/Reminder letter depending on what the participant needs to complete at this time.
- Interviewers make up to 10 attempts to reach the MOIB and remind her to return her bloodspot and infectious disease linkage consent forms and participate in the stillbirth interview. After 10 attempts and only if the 24 month timeline of completing both the BD-STEPS core and stillbirth interview has been reached, we code the case as aged out and cease making attempts for the completion of the Stillbirth Supplementary Interview. If the 24 month timeline has not been reached, the attempts could be continued every 30 days until the mother has aged out.
  The interviewer leaves a message the 1st, 4th, and 8th time they reach an answering machine and every 6$^{th}$ time after 10 attempts.
- A message is also left if the interviewer called for an appointment and the MOIB did not answer, to let her know that we called as planned.
- The interviewer scheduler delays a case for two days after an interviewer records that she left a message on an answering machine. However, interviewers can manually override this delay if needed.

## Number and Frequency of Call Attempts

- Non-contact attempts result in a delay in subsequent calls to the same phone number for at least 57 hours. The delay may be longer depending on the nature of the non-contact attempt.
  - For example, leaving a voice mail is considered a non-contact attempt where future call attempts would be delayed by 2 days.

- Call attempts may also be delayed in response to hang-ups, non-cooperation events that are not final refusals, mailing events, and by interviewer or case manager discretion.
- Per Massachusetts' request, we make no more than
  - 20 non-busy signal calls and leave no more than 5 voicemails to a given phone number over a 3-month time period
  - 10 non-busy signal calls and leave no more than 2 voicemails to a given phone number within a specific week.
- Once contact is made with the study subject and they indicate interest in participating in the study, these parameters are re-set for MA cases.

### *Other Calling Parameters*

- Best Time to Call (BTC). Some Centers provide BTC information as part of the upload file, usually in the form of comments. When provided, this information is pulled into CATI as a case level comment available to the interviewer for review prior to dialing. In addition, Centers may provide this information to the case manager, who adds it to the CATI comments. Also, MOIB or other household members may provide information about BTC during call attempts. Such information is often entered in the case history but also (or instead) may be added as a case level comment. Interviewers review the comments and the case history prior to each call and use guidance from training to make informed decisions about when to call.
- Guidance for interviewers on BTC is as follows:
  - Focus calling on BTC for the first three attempts after BTC notes were entered. After those three attempts have been made, if the notes indicate the BTC are *not the only* acceptable times to call, then start trying at other times as well.
    - ✓ If MOIB asks why we called outside of the BTC range, explain that we have tried at the times originally suggested but had not reached her.
    - ✓ Ask if the originally suggested time frame is still the best, or if there is another time frame that is better, and attempt to set a soft or hard call back at that time (assuming MOIB is not able to complete the interview on current call)
- Business and Work Numbers. The interviewer may obtain business or work numbers from Centers or from tracing.
  Call business and work numbers as you do other numbers. However, please note the following instruction from your voicemail script sheet: "Be very careful about leaving messages at subject's place of work. Leave message only if work voicemail identifies mother/subject directly." And note that there is a separate answering machine script for MOIB's work voicemail.

**Appointment Reminders**. Before making an appointment, interviewers ask whether the mother or gatekeeper would like a reminder before the appointment. If the answer is yes, then the

interviewer asks if they prefer to receive a reminder by email or by text. They ask for the email address or phone number to which they should send a reminder. Reminders for same-day and next-day appointments are sent shortly after requested. Email reminders for other appointments are sent the day before the appointment.

- If the mother returns her bloodspot consent or completes her SB interview before the reminder contact is complete, the workflow codes the bloodspot reminder and SB interview reminder stage as closed and interviewers cease making attempts to reach the mother.

## Supplemental Stillbirth CATI

See Att36 – BDSTEPS_SB-Suppl Questionnaire (English and Spanish)

## Stillbirth Supplemental Questionnaire Priority

Women with a stillbirth with birth defect will not be contacted for the online occupational questionnaire until they have either completed the stillbirth questionnaire or have aged out (at 24 months from EDD). Control women who are eligible for the stillbirth supplement questionnaire will NOT be held from receiving the online occupational questionnaire until they have completed the stillbirth supplemental interview or have aged out (at 24 months from EDD). Women with stillbirth without birth defect are not eligible for the online occupational questionnaire.

## Additional Letters

The following letters follow the BD-STEPS protocol; for additional guidance, see BD-STEPS Protocol.

**No Response Letter** (BD-STEPS-Att40 SB-Supp_NoResponseLetter_Eng*) This letter is sent when there is no response from study subject to introduction letter for interview and/or phone calls from the interviewer.

**Inclomplete Survey** (BD-STEPS-Att41 SB-Supp_IncomplIntv_Eng*) This letter is sent when there is a partial interview for a study subject and we want to contact in an attempt to get woman back on phone to complete.

**Final No Response Letter** (BD-STEPS-Att43 SB-Supp_FinalNoRespLtr_Eng*) This letter is sent a few months before woman “ages out” as a last attempt to get her to participate

**General No Contact Letter** (BD-STEPS-Att39 SB-Supp_GenNoContactLet_Eng*) In the protocol for core interview this letter is referred to as the “California General letter” because it was CA Center’s idea to have one letter to replace the no response letter, the final letter (and not part of the Stillbirth protocol, the soft refusal letter). This letter can be used INSTEAD of the no response letter or final letter if Center chooses OR not at all.